MedSun: Newsletter #45, February 2010

Articles

Hettich Centrifuges with 2050 and 2076 Plastic Rotors: Recall

Print Item
E–mail Item

FDA MedWatch Safety Alert

FDA notified healthcare professionals of a Class I recall of Hettich Centrifuges with 2050 and 2076 plastic rotors, used in combination with the Mikro 12-24, Mikro 20, Haematokrit 20 and Haematokrit 24 bench top plastic centrifuges. The recall was initiated because the plastic centrifuge rotor may crack, break apart and be forcefully ejected through the plastic centrifuge housing at a high rate of speed. This may result in serious personal injury and damage to the surrounding area.

Additional Information:

FDA MedWatch Safety Alert. Hettich Centrifuges with 2050 and 2076 Plastic Rotors: Recall. January 28, 2010.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm199202.htm[7]

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Infusion Set Needles [Manufactured by Nipro for Exelint]: Recall

Print Item
E–mail Item

FDA MedWatch Safety Alert

FDA notified healthcare professionals of a Class I recall of Exel/Exelint Huber needles, Exel/Exelint Huber Infusion Sets and Exel/Exelint "Securetouch+" Safety Huber Infusion Sets, manufactured by Nipro Medical Corporation for Exelint International Corporation due to 'coring', the cutting or dislodging of silicone cores or slivers from the ports into which they are inserted.

Additional Information:

FDA MedWatch Safety Alert. Infusion Set Needles [Manufactured by Nipro for Exelint]: Recall. January 26, 2010.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm198728.htm[9]

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Nipro GlucoPro Insulin Syringes: Recall

Print Item
E–mail Item

FDA MedWatch Safety Alert

Nipro Medical Corporation and FDA notified healthcare professionals of a voluntary nationwide recall of all GlucoPro Insulin Syringes. These syringes may have needles that detach from the syringe. If the needle becomes detached from the syringe during use, it can become stuck in the insulin vial, push back into the syringe, or remain in the skin after injection.

Additional Information:

FDA MedWatch Safety Alert. Nipro GlucoPro Insulin Syringes: Recall. January 22, 2010.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm198445.htm[11]

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ev3 Endovascular Inc. Trailblazer Support Catheter: Class I Recall

Print Item
E–mail Item

FDA MedWatch Safety Alert

This device may crack near the radiopaque marker band. This may result in serious patient injury, including insufficient oxygen supply to the tissues, damage to blood vessels, heart attack, limb amputation, unplanned surgery, and/or death.

Additional Information:

FDA MedWatch Safety Alert. ev3 Endovascular Inc. Trailblazer Support Catheter: Class I Recall January 5, 2010.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm196266.htm[13]

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LabNet

Rapamune (sirolimus): Drug Monitoring Recommendations

Print Item
E–mail Item

FDA MedWatch Safety Alert

Wyeth notified healthcare professionals of changes to the Rapamune Prescribing Information regarding changes in the performance of an immunoassay used for therapeutic drug monitoring (TDM) of sirolimus. The TDM results reported from the assay are both assay and laboratory-dependent. In addition, the results may change over time. Therefore, adjustment to the targeted therapeutic range must be made with a detailed knowledge of the site-specific assay used. It is critical that the clinician caring for a patient on sirolimus maintain communication with their laboratory to determine whether the assay used for measuring sirolimus concentrations has been changed.

Additional Information:

FDA MedWatch Safety Alert. Rapamune (sirolimus): Drug Monitoring Recommendations. January 11, 2010.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm197059.htm[15]

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Interpretive Comments on Test Results: How Far Should Labs Go?

Print Item
E–mail Item

AACC Clinical Laboratory News

With today's focus on patient safety, diagnostic errors have been put in the spotlight. Whether the result of systemic mistakes by an organization or those of individual clinicians, some reports have noted clinicians' failure to correctly interpret diagnostic tests, pushing the problem uncomfortably close to the walls of the lab. One explanation put forward for missed diagnoses is the sheer volume of information clinicians need to process in order to do their jobs. In order to help clinicians understand test results, some labs have turned to including interpretive comments on their lab reports. Those labs experimenting with interpretive comments say they tread a fine line between helping physicians assimilate information from the lab without contributing to the information overload so pervasive in medicine.

Additional Information:

AACC Clinical Laboratory News. Interpretive Comments on Test Results: How Far Should Labs Go? Malone, Bill. December 2009.
http://www.aacc.org/publications/cln/2009/December/Pages/CoverStory2Dec09.aspx[17]

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HomeNet

Human factors and ergonomics in home care: Current

Print Item

concerns and future considerations for health information technology

E–mail Item

PubMed Abstract

Sicker patients with greater care needs are being discharged to their homes to assume responsibility for their own care with fewer nurses available to aid them. This situation brings with it a host of human factors and ergonomic (HFE) concerns, both for the home care nurse and the home dwelling patient, that can affect quality of care and patient safety. Many of these concerns are related to the critical home care tasks of information access, communication, and patient self-monitoring and self-management. Currently, a variety of health information technologies (HITs) are being promoted as possible solutions to those problems, but those same technologies bring with them a new set of HFE concerns. This paper reviews the HFE considerations for information access, communication, and patients self-monitoring and self-management, discusses how HIT can potentially mitigate current problems, and explains how the design and implementation of HIT itself requires careful HFE attention

Additional Information:

PubMed. Human factors and ergonomics in home care: Current concerns and future considerations for health information technology. 2009. http://www.ncbi.nlm.nih.gov/pubmed/19713630?ordinalpos=&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.SmartSearch&log$=citationsensor[19]

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KidNet

Children are commonly harmed by adverse events in intensive care units.

Print Item
E–mail Item

AHRQ

When adverse events (AEs) occur in pediatric intensive care units (ICUs), one-third of such incidents result in physical injury to children, while two-thirds harm children in other ways, according to a new study. Johns Hopkins researchers analyzed data collected over a 2-year period describing safety incidents taking place in pediatric ICUs around the country. Providers were able to report such incidents and near misses through a Web-based incident reporting system called the Intensive Care Unit Safety Reporting System. During the 2-year study period, 23 pediatric ICUs reported 464 incidents. Patient contributing factors were the strongest predictor of harm, and training and education factors also played a role. To improve safety in pediatric ICUs, the researchers

recommend developing protocols for high-risk procedures involving lines and tubes; improved monitoring; and staffing, training, and communication initiatives.

Additional Information:

AHRQ. Children are commonly harmed by adverse events in intensive care units. 2009. http://www.ahrq.gov/research/nov09/1109RA3.htm[21]

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Highlighted MedSun Reports

Highlighted Reports

Print Item
E–mail Item

This section contains a sample of reports from all the MedSun reports received during a particular period. The reports were submitted by MedSun Representatives. In some instances the reports have been summarized and/or edited for clarity. The entries that follow represent a cross section of device-related events submitted by MedSun reporters during the period November 1 through November 30. All other reports can be searched under the 'MedSun reports' menu pane. Note: the two month delay is due to quality control and follow-up.

GENERAL HOSPITAL

Device:

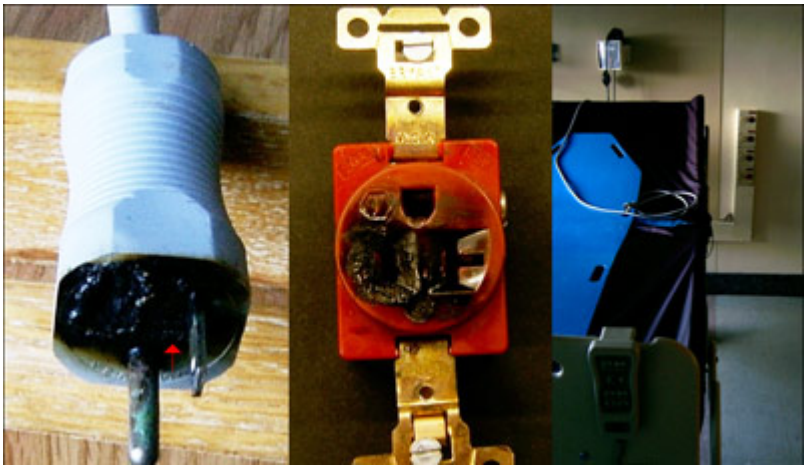
Type: Bed, Hospital, Bariatric
Manufacturer: SizeWise Rentals, LLC
Brand: Lowboy (35" Wide)
Model #: 33060050

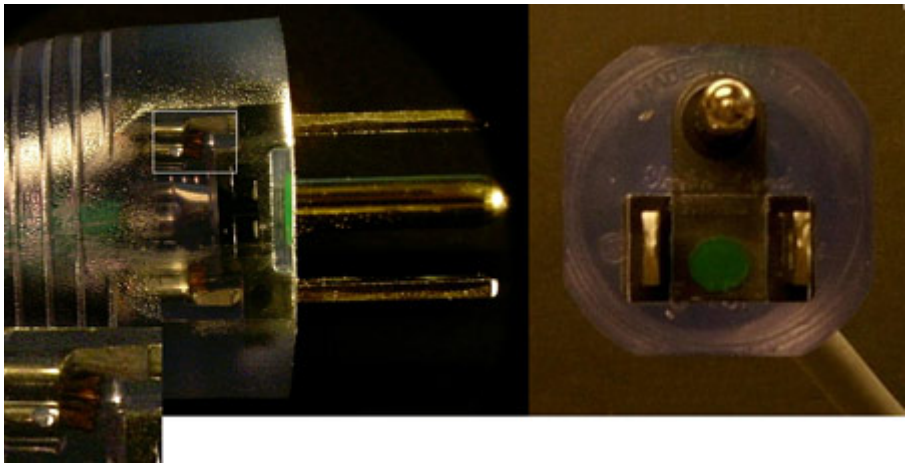
Problem:
As a nurse started to raise a SizeWise LowBoy bed from its lowest position, smoke started to come from the AC receptacle where the bed's power cord was plugged in. The power cord was unplugged (by pulling on the cord) leaving the bed (and patient) in a lower position than desired. Patient was moved to another bed and to another room.

Manufacturer response (as per reporter) for Hospital bed, LowBoy (35" wide)

I informed our rental rep (we only rent these beds when needed), and the rental company, of the event and of the problems other manufacturers have had with this same type of power cord plug.

See device images:





Device:

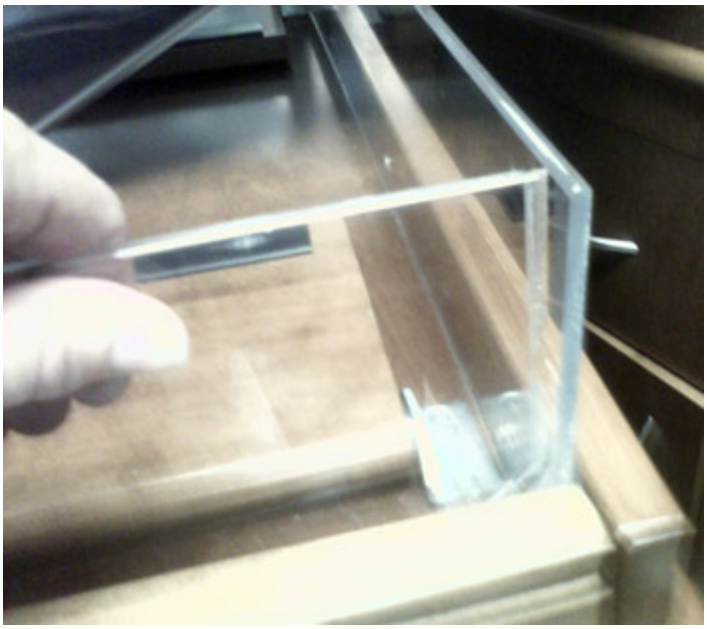
Type: Bassinet, Infant
Manufacturer: Nemschoff
Brand: Newborn Bassinets

Problem:
Since early winter this year, we have had problems with our newborn bassinets cracking, breaking, and developing holes in the corners. Drawers/doors swing open and won't stay closed, carts hard to push, wheels don't roll smoothly. Plexiglas piece along the top of the bassinets were all replaced by the company approximately four months ago. Currently have 11 bassinets not usable. Have pictures of problems I can send.

Manufacturer response (as per reporter) for Bassinets that fit into wooden carts, Newborn bassinets: Initially the company stated that the carts/bassinets were not being handled correctly. Plexiglas parts were replaced and they are all breaking/cracking again. Representative came again and took pictures and I took pictures. We asked if any other

facility was having a problem.

See device images:

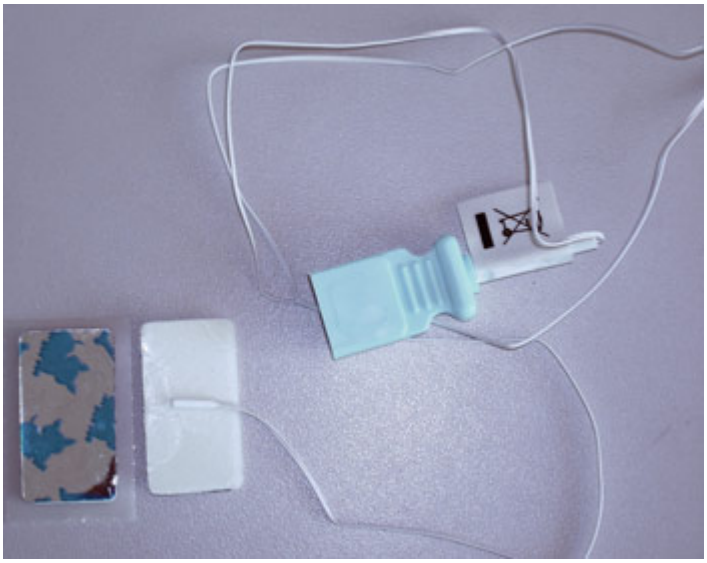


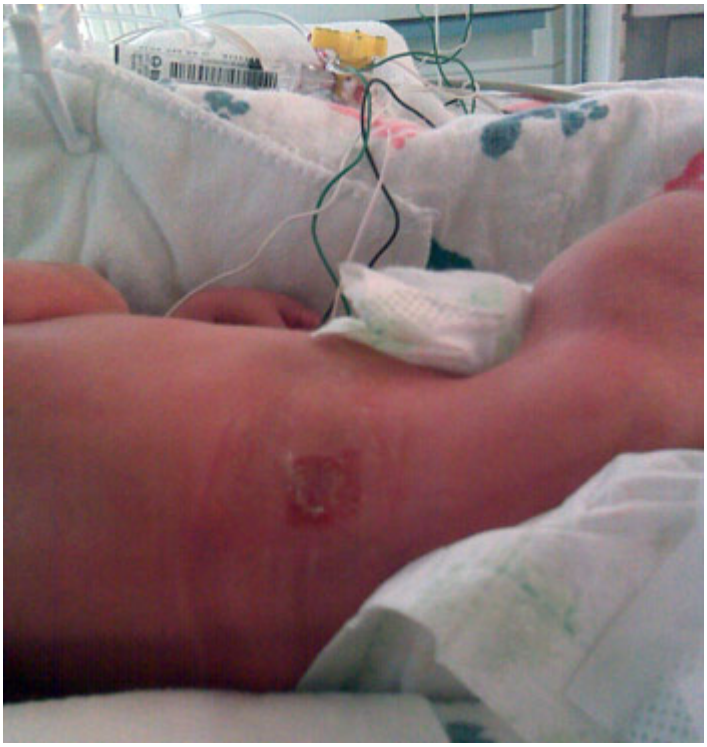
Device:

Type: Cover, Skin Temperature Probe
Manufacturer: Coviden Kendall
Brand: Neonatal/pediatric Temperature Cover
Cat #: MI30002

Problem:
Noted area of skin breakdown directly under temperature probe cover on infant's right side of back. Area measured approx 2.5cm X 3cm. Area appeared excoriated almost like a burn, with discolored drainage formed on top of wound. The burn probably was a second degree burn. The nurse did not report any damage to the pad.

See device images





Device:

Type: Indicator, Sterilizer, Biologic And Condition
Manufacturer: Getinge
Brand: Biosign Ssi
Model #: 61301605372
Lot #: 2417C

Problem:
Purple indicators did not completely turn to green.

Manufacturer response (as per reporter) for Biosign SSI test pack, SSI test pack

Phone call placed to Rep

Device:

Type: Pump, Infusion, Implanted, Programmable
Manufacturer: Medtronic Neuromodulation
Brand: Synchromed Ii
Model #: 8637-20

Problem:

Medtronic pain pump failed, it was replaced along with a new catheter.

Comment from FDA: Please see recall on this product online available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=83826

Device:

Type: Iv Tubing
Manufacturer: B. Braun Medical, Inc.
Brand: Ultrasite Iv Set For Outlook Safety Infusion System
Model #: 375196
Cat #: US3140

Problem:
We experienced two episodes with defective Braun primary IV tubing today in the ICU. The first episode involved the injection port on the primary infusion line closest to the patient. The port was leaking out a significant amount of blood on a critically ill patient. The port was used for injection prior to finding the leak.

The second episode was similar, but involved a different patient and the injection port immediately after the pump. Again, the patient was bleeding back and out of that port with a significant amount of blood collected on the floor. Another nurse reported the same type of defect on an IV tubing last week. She saw that the blue stopper did not pop back up after injection.

Device:

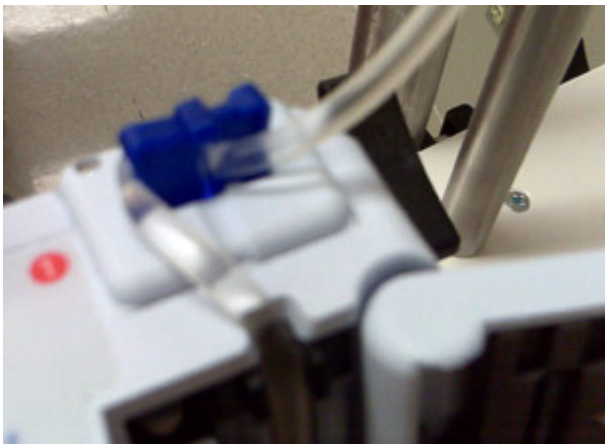
Type: Infusion Pump
Manufacturer: Sigma International
Brand: Spectrum

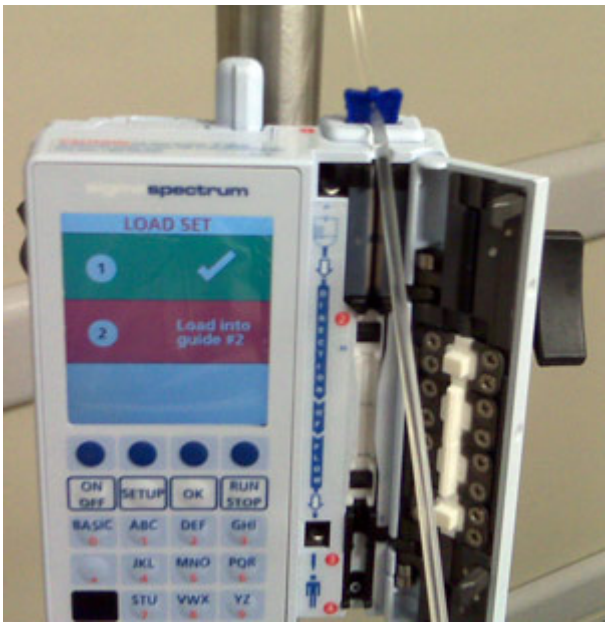
Problem:
IV tubing was inadvertently loaded backwards in the infusion pump which could have resulted in medication not being administered and patient's blood being drawn back into the IV line. Because of complex conversion process at our facility to the new infusion pumps, we requested manufacturer to wait until the install was completed before discussing this issue with us. The Manufacturer responded with additional training when the misloaded tubing was discovered.

We feel that the design of pump channel and/or IV tubing loading process allows a clinician to easily misload IV tubing if the clamp slides too far down the tubing (away from the first access port). The loop caused by this positioning of the clamp (which is also the key to open the pump door) made it difficult to determine which tube was the distal end of the tube.

We attempted various ways to misload the tubing in a way that will "trick" the pump into working, and found two ways to do this easily. The pump design relies on its labeling as well as the nurse remembering to trace the IV line from the bag to the patient on every load. There does not seem to be any safe guard against this human factor in the design of the pump. However, the pump does alarm with an “occlusion” if it is started with misloaded tubing, but there is nothing to prevent the tubing misload from happening in the first place.

See device images





Device:

Type: Iv Tubing Set
Manufacturer: B. Braun Medical, Inc.
Brand: Ultrasite Iv Set For Outlook Safety Infusion System
Cat #: 3751196
Other #: US3140

Problem:
The patient had IV fluid being infused by a B. Braun Outlook 100 infusion pump. The nurse noticed something dripping in the area of the IV tubing. Upon further assessment she noticed that the NSS was dripping out of the tubing proximal to the patient, past the IV pump. The inner blue portion of the ultrasite valve was depressed within the white plastic exterior and it did not recoil. The fluid was dripping out of the ultrasite valve and air was being drawn into the tubing. The air was noticed before it reached the patient and no harm occurred to the patient.

The only explanation the nurse had for the failure is that a syringe may have been connected to the port to deliver medication, and when it was removed, the plunger did not return to the closed position. However, that has not been verified.

Manufacturer response (as per reporter) for IV tubing Set, Ultrasite IV set for Outlook Safety Infusion System:

They requested the tubing set so that they can evaluate it. The sales representative stated that this not a common problem and he has not experienced this problem.

See device images

GENERAL & PLASTIC SURGERY

Device:

Type: Cautery Device, Thermal, Disposable, Battery Powered
Manufacturer: Bovie Medical Corporation
Model #: AA01
Lot #: 0709A

Problem:
Patient's eyelashes flamed as surgeon cauterized incision(in the eyelash area). Sponge laid on flame to extinguish. Eyelashes stopped burning, but the sponge then ignited, but was put out. There was a plastic corneal protector in place during episode.

Device:

Type: Endoscopic Vein Harvesting Kit
Manufacturer: Sorin Group USA Inc.
Model #: KTV15
Lot #: 0921500032

Problem:
Two bipolar devices broke while being used in the patient's leg. All pieces were removed.

The piece is the clear portion that was under the black cap. There was no patient injury.

Manufacturer response (as per reporter) for Bipolar Device, Endoscopic Vein Harvesting Kit

As of this week the manufacturer has offered replacement lots.

Comment From FDA: Please see recall online available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=87081

Device:

Type: Cryotherapy System
Manufacturer: COOPERSURGICAL, INC.
Brand: Leisegang
Model #: LM-900

Problem:
Patient came for cryotherapy of cervix. As procedure ended, cryotherapy spurted to the right side of the patient's vagina. Subsequently, she presented with swelling and pain on the right side of her vagina. She has a healing area on her right labia minora that is being treated with premarin cream. The equipment was evaluated by manufacturer and an O-ring was replaced to prevent future occurrence. Failure of the o-ring caused liquid nitrogen to be ejected from device.

Device:

Type: Implant, Vaginal
Manufacturer: Boston Scientific
Brand: Uphold
Model #: UPN M0068317080
Lot #: OML 9092205

Problem:
Bullet on Capio Suture broke off on an Uphold Vaginal Implant, with mesh leg fixation, Boston Scientific. We were unable to use the implant due to broken suture. No patient harm. Broken piece attached to package, will be returned to company for evaluation.

Device:

Type: Table, Operating Room
Manufacturer: STERIS CORPORATION
Brand: Steris
Model #: 3080SP

Problem:
During transfer of the patient from the stretcher to the Operating Room table (which was in the locked position), the bed moved away at the foot of the bed causing the patient to slip between the OR table and the stretcher. The OR team lowered the patient to the floor, however, the patient hit her head on the OR table during the decent, resulting in a small laceration to the head. CT scan of the head and sacrum were negative for any acute injury. This event did not extend the patient's length of stay.

Device:

Type: Saw, Sternal
Manufacturer: STRYKER INSTRUMENTS
Brand: Stryker
Other #: Pack # EHD Sternal Saw

Problem:
After cutting the patient's sternum with the regular Stryker saw, the surgeon noted that there was oil in the patient's wound. The saw was passed off the sterile field immediately. The sternum was irrigated with warm lactated ringers solution and Ancef by the surgeon. It was found that after maintenance of the saw was completed by Stryker, the hand piece was not resealed appropriately to prevent lubrication from leaking from the hand piece.

Device:

Type: Handpiece, Esu, Tissue Sealing
Manufacturer: Valley Lab, Tyco Healthcare Group
Brand: Ligasure Impact
Model #: LF4200
Lot #: 166603
Cat #: 20667085011693
Other #: 317000917

Problem:
During the procedure, the product failed to open while in use. Jaws of product on tissue without incidence. Surgeon was unable to open handle and continue use of the product. No harm to patient.

Device:

Type: Laser Fiber
Manufacturer: Vascular Solutions, Inc.
Brand: Vari-lase
Lot #: 546508

Cat #: ref #7112
Other #: Vari-lase Standard Kit 45 FR 45 CM Sheath

Problem:
Patient admitted to Outpatient Surgery Center for right anterior lateral greater saphenous vein endovenous laser ablation with multiple stab phlebectomies. Vari-Lase laser was used. A Vari-Lase standard kit, 4fr, 45 cm sheath was opened per physician's request.

Sheath was placed. Laser fiber was advanced through the sheath. Click/lock method was used to hold the laser fiber in the sheath, although I (the surgeon) felt that the lock mechanism was a bit loose. I started the laser and pulled back the sheath and fiber together, burning 100 Joules per centimeter, total length of 16 cm. When I pulled the laser fiber out through the skin incision, the laser fiber was flush with the sheath rather than protruding 2 cm as is standard. The tip of the sheath was singed and, while I do not think that any part of the sheath was burned into the anterior lateral GSV, I cannot be completely sure that there are no residual burned pieces of plastic sheath within the patient. I looked to the click/lock mechanism which holds the laser fiber stationary within the sheath and the mechanism had come undone and the laser fiber was moving freely within the sheath. I had the sheath and laser fiber saved for further evaluation.

RN circulator in the room called the vascular lab at the request of Dr. for nurse to bring another ultrasound machine to the room. Ultrasound was performed and no pieces of plastic were noted by either nurse or Dr. The patient remained stable during the procedure. After the procedure the patient's husband was brought to the conference room by Dr. and RN was also present for the conversation while Dr. explained the incident to the husband. It was also explained to the patient. Dr. told the patient and husband potential complications to be aware of.

Device:

Type: Laparoscope Camera & Light Cord
Manufacturer: Unknown
Brand: Unknown

Problem:
Starting a Laparoscopic Operative case using a camera and scope, the light cord to the scope was thrown off the foot of the table to be plugged into the light source box. Light source was plugged in, and not put on standby, leaving the light source just sitting on the field. The light source got hot and caught my gown. I looked down and saw smoke coming from my gown, which I immediately removed and noticed that the fire had gone through the gown and on to my scrubs. It burned a hole through the gown and scrubs. I removed the gown and stopped the burning before it hit my skin. I was not burned. The drapes where not damaged and patient was not hurt in any way.

CARDIOVASCULAR

Device 1:

Type: Catheter, Central Venous
Manufacturer: Cook Medical, Inc.
Brand: Spectrum Glide

Device 2:

Type: Catheter, Central Venous
Manufacturer: Cook Medical, Inc.
Brand: Spectrum Glide
Cat #: G49804

Device 3:

Type: Catheter, Central Venous
Manufacturer: Cook Medical, Inc.
Brand: Spectrum Glide
Cat #: G50821

Device 4:

Type: Catheter, Central Venous
Manufacturer: Cook Medical, Inc.
Brand: Spectrum Glide
Cat #: G50822

Problem:
Multiple reports involving multiple patients and practitioners regarding Cook triple lumen catheters clotting either during insertion or shortly thereafter. Involves one (1) to three (3) ports of the catheters. In comparison w/ three other catheter manufacturers, Cook catheters clotted 50% of the time while other catheters clotted 25% or less, and others had no problems on insertion. No change in physician techniques noted. Issue occurs in multiple patient care units; mostly ICUs where the majority of central lines are used.

Device:

Type: Defibrillator, External
Manufacturer: Philips Medical Systems
Brand: Heartstart Xl
Model #: M4735A

Cat #: M4735A

Problem:
Atrial fibrillation was sustained and required repeated cardioversions. A 200J biphasic shock did not correct the atrial fibrillation with 4 attempts. Pads were reapplied on the anterior chest with "physician pushing on pads" and 200J biphasic shock was successful in returning sinus rhythm. Note: This area is trying to get new defibrillators that are >300J and we are questioning the clinical justifications as there are mixed messages about the effectiveness.

Comment from FDA: Please see the communications, "Energy Levels in External Biphasic Defibrillators: Initial Communication," online available: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm189259.htm and The Patient Safety News story, "Energy Levels in External Biphasic Defibrillators" online available: http://www.accessdata.fda.gov/psn/transcript.cfm?show=94#7.

Device:

Type: Laser, Endovenous Device
Manufacturer: InaVein, LLC
Brand: Trivex
Model #: InaVein TRIVEX System

Problem:
Patient was scheduled for a left saphenous vein right femoral artery with Trivex, prone and supine. The Trivex machine worked perfectly for the first half of the case while the pt was in the prone position. The patient was turned, and proceeded on with the supine portion of the case. The Trivex was working well for about 20 mins or so and then the resector portion stopped working. At this time, the resector was re-examined. The resector handpiece was taken apart and the non-disposable portion has a wheel that spins to turn the blade on the disposable resector. The wheel was not spinning. The Trivex machine was turned off and on several times. The handpieces were plugged and unplugged. At this point the lights on the machine (that are supposed to be green) have turned orange and will not turn back to green. Biomed and charge nurse were notified. Biomed tech came to the OR to inspect the machine. She did all the things that we did as well. We also opened a new disposable and non-disposable handpiece resector. These changes did not help. Tech left the room to read the manual on the Trivex. She came back and stated that from our description, the responses from the machine and from the manual that it appeared to be a motherboard failure. Surgeon finished the rest of the case with stab phlebectomies. No immediate harm came to the pt from the machine not working.

Device:
Type: Catheter, Atherectomy, Peripheral Artery
Manufacturer: Pathway Medical Technologies, Inc.

Brand: Jetstream G2 Nxt
Model #: PV20300
Lot #: 090805
Other #: Jetstream G2 NXT 2 1/3.0mm Atherectomy Catheter

Problem:
Patient in Cath Lab for atherectomy of his leg vein. Patient suffers from claudification of that extremity. Cardiologist was performing procedure using a Jetstream G2 catheter to remove part of the tissue when it stopped working. Per the MD, the device "froze up". The catheter was removed by the MD, inspected and then re-inserted to use again. However, the catheter did not function as the MD wanted it to so the decision was made, by the MD, to switch modes and perform an angioplasty instead. Procedure was finished and patient sent to CVCU for recovery. No injury or harm to patient but MD did perform alternative procedure to remedy patient's problem.

Device:

Type: System, Thermal Regulating
Manufacturer: MEDIVANCE, INC
Brand: Arctic Sun
Model #: 2000
Cat #: 2000-02 or 2000-02L

Problem:
Patient had been on Arctic Sun external cooling for management of neurogenic fevers for 6 days. When pt was turned on the evening of the 6th day, RN found a large blister on back and thighs where the cooling pads had been applied. Two days later the injury was described as frostbite and may be full thickness. Follow-up treatment with silvadene and debrided a few days later. Clinicians are treating it like a burn.

Pads used with the Arctic Sun Cooling Device were product # 317-00 Universal Lot# K9E1804
product # 317-09 Large Lot# K9K0502
Pads were discarded at time of incident.

RADIOLOGY

Device:

Type: Mri, 3t
Manufacturer: Siemens Medical Solutions USA, Inc.
Brand: Verio
Other #: Body Array Coil 3T magnet

Problem:
Patient has 2 screws in her right calcaneus. During the exam the patient was repositioned several times, due to patient complaining that her heel was burning. The exam was stopped.

Device:

Type: Mri, 3t
Manufacturer: Siemens Medical Solutions USA, Inc.
Brand: Verio
Other #: Body Array Coil 3T magnet

Problem:
Patient came to MRI for a brain MRI with and without contrast. Patient had a known fusion at C6-C7. After the scout was done and 1 set of images was done -totaling 2 minutes- the patient stated that her hair felt hot. Tech checked her hair and it did feel abnormally warm to touch. Radiologist examined patient, waited until her hair cooled down, then attempted to proceed with the MRI. The exam was started, again the patient felt hot, and the exam was aborted. Patient stated that her scalp hurt, felt like a sunburn.

Device:

Type: Mri, 3t
Manufacturer: Siemens Medical Solutions USA, Inc.
Brand: Verio
Other #: Body Array Coil 3T magnet

Problem:
Patient sent to MRI for a scan; did not notify the providers that she had a previous surgery or that she had an implanted rod in her spine. During the scan, the patient complained that her back was hot. The MRI was aborted.

Device:

Type: Brachytherapy, Hdr Afterloader
Manufacturer: Varian Medical Systems, Inc.
Brand: GammaMedPlus
Model #: GammaMedPlus

Problem:
A biohazard leak is believed to have been incompletely decontaminated.
This patient was treated with a Miami applicator with a condom over it. There were no signs of a breach of the closed system for this patient.
On the day of the procedure, the patient (index patient) was treated with the HDR (high dose rate) unit. During setup for the procedure, a stopper was removed from part of the

equipment because it did not fit well. After the procedure, inspection of the transfer tubes found biological fluid in the specimen.

The vendor, was contacted at the time and came on-site to decontaminate the equipment. The service engineer used the physics QA (or transfer) tube to remove the contaminated wire.

Approximately 2 weeks later, a different Varian engineer came on-site for routine maintenance. Upon discussion and inspection, it was determined that unit should be considered contaminated because the Physics QA (or transfer) tube was used during the decontamination process, thus contaminating that tube. That tube had continued to be used prior to subsequent further decontamination, therefore all parts of the unit that have been in contact with the wire and all related equipment are being treated as contaminated.

All of these involved patients were treated with this closed system.

The vendor is replacing the necessary equipment so that there is no risk for future patients.

GASTROENTEROLOGY & UROLOGY

Device:

Type: Dialysis Machine
Manufacturer: Fresenius Medical Care North America
Model #: 2008K

Problem:
The Fresenius hemodialysis machines AC power cord with the black plastic bridge, which is manufactured by a power cord manufacturing company exhibited charring at the neutral wire in the molded clear colored plug.

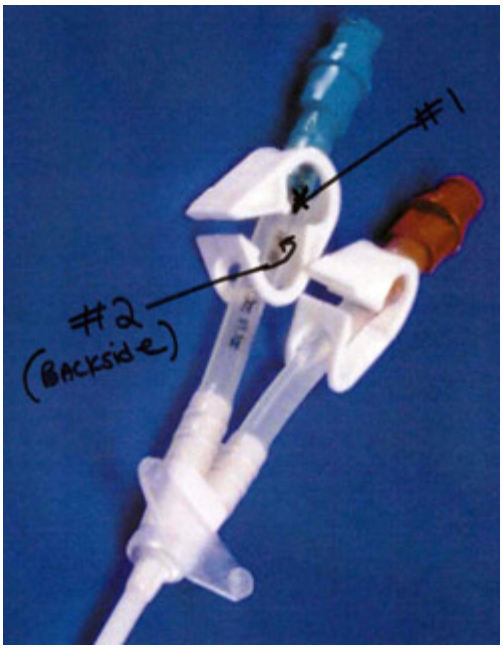
See device image

Device:

Type: Dual lumen catheter
Manufacturer: Covidien Kendall
Brand: DL Mahurkar Dialysis Catheter
Cat #: 8813793009

Problem:
A patient was undergoing a stem cell collection through a right internal jugular DL Mahurkar catheter. It was noted that there was a pin hole leak in the plastic tip of the blue lumen of the (11.5F/16 cm DL Mahurkar Dialysis catheter) catheter. The catheter was pulled. The patient had enough stem cells collected from a prior day and the catheter was no longer needed. In addition a similar occurrence with another patient happened about a month earlier to this reported event where a pin hole was noted in the same catheter. This occurred with a different size catheter (11.5F/19.5cm DL Mahurkar Dialysis Catheter). The pin hole was also noted in the plastic tip of the blue lumen while the patient was undergoing stem cell collection. This patient returned to interventional radiology to have another catheter inserted and the stem cell collection procedure was resumed the following day.

See device image



Device:

Type: Hemodialysis, Continuous Renal Replacement Therapy
Manufacturer: Gambro Renal Products, Inc.
Brand: Prismaflex
Model #: Prismaflex

Problem:
There was a malfunction of the Prismaflex. The machine was restarted twice. Reviewed alarms and took steps per rep's guidance through Gambro's help line to resolve. Staff unable to clear alarm that pre-blood pump scale component was missing. The machine was running with yellow light. Gambro’s recommendation was to end treatment, flush blood back to patient, and disconnect due to machine malfunction of scale. A different machine was acquired and now running without difficulty.

Device:

Type: Hemodialysis, Continuous Renal Replacement Therapy
Manufacturer: Gambro Renal Products, Inc
Brand: Prismaflex
Model #: Prismaflex

Problem:
Prismaflex continuous renal replacement therapy machine lost memory for one hour's worth of fluid totals and the recorded patient weight. The next two hours the machine took off more fluid than it should have without any alarm sounding. The Prismaflex

support line was called and machine was taken out of service. A new machine was set up. This delay caused a roughly three and one-half hour lapse of therapy and resulted in the patient requiring an increase in pressor therapy.

Device 1:

Type: Hemodialysis, Continuous Renal Replacement Therapy
Manufacturer: Gambro Renal Products, Inc.
Brand: Prismaflex
Model #: Prismaflex

Device 2:

Type: Hemodialysis, Continuous Renal Replacement Therapy
Manufacturer: Gambro Renal Products, Inc.
Brand: Prismaflex
Model #: Prismaflex

Problem:
Continuous renal replacement therapy (CRRT) machine in use when filter clotted off. A new system initiated, and "Air in Line" alarm received without a way to clear. New CRRT machine attained, when turned on was "stuck" in the reprime screen. Device turned off and then back on; same screen appeared. This step repeated with same result. Dialysis called, and was instructed to turn off again and restart. The screen did not change. Dialysis notified and told to get a new machine. Attained new machine, and started priming. During prime test machine failed at 2nd bar multiple times. Dialysis called and new machine delivered pre-primed. Previous two machines placed in dirty utility room with signs placed on the machines with descriptors of problems. Devices transported to BioMed a few days later.

Device:

Type: Hemodialysis, Continuous Renal Replacement Therapy Tubing
Manufacturer: Gambro Renal Products, Inc.
Brand: Prismaflex Hf 1400 Circuit
Lot #: 8399040
Cat #: Prismaflex HF 1400 circuit

Problem:
Prismaflex circuit changed on evening shift due to 96 hour limit. New circuit had to be replaced at midnight due to inability to recover from pressure alarms.

This circuit started without incident. An extra manual prime was done. Large amount of foam developed in the deaeration chamber, which was removed multiple times with syringe. The foam continuously reaccumulated, and it appeared to be from the purple line

initially where it enters the deaeration chamber. It was later noted that small bubbles were at the top of the filter in the blood line when the blood was being returned. All connections were checked and double checked. Attempted to change the rate of the post replacement fluid. This did not change the rate of foam accumulation. A new circuit was then started with a full re-prime of the circuit. There were no issues with this circuit.

Device:

Type: Hemodialysis, Continuous Renal Replacement Therapy
Manufacturer: Gambro Renal Products, Inc.
Brand: Prismaflex
Model #: Prismaflex

Problem:
Continuous renal replacement therapy (CRRT) hemofilter Memory error Code 6 alarm when attempting to adjust fluid removal rate. Self test alarmed. When self test completed patient fluid removal remained highlighted. However, at first attempt to continue to adjust fluid level, memory error 6 alarmed. Attempted to turn off/on and unplug filter, but filter still clotted. Staff unable to return blood to patient. Surgical Critical Care notified . A new filter obtained and CRRT resumed.

Device:

Type: Hemodialysis, Continuous Renal Replacement Therapy
Manufacturer: Gambro Renal Products, Inc.
Brand: Prismaflex
Model #: Prismaflex

Problem:
Prisma citrate bags were bone dry. The system did not alarm. The system took in air, and machine stated "system failure in need of maintenance"...enough air was in line that machine shut down.

The PrismaFlex dialysis machine went down and this could have been a potential disaster. Risk Management was made aware. The machine continued to infuse air, the alarm did not go off, and the message came up for "System failure". The citrate bag line sucked in air--there was so much air that they could not recirculate blood.

I inquired on the patient status and was informed that this has happened to this patient with this machine before. She can be off dialysis for a short time.

This machine goes down after 18-30 hours for this patient. Earlier in the day they had a back up machine, but that was used for another patient and the hospital does not have any other machines available.

Device:
Type: Electrode, Esu, Hook
Manufacturer: Richard Wolf Medical Instruments
Brand: Hook Electrode
Lot #: 732081

Problem:
During cystoscopy and incision of ureterocele the insulation on the sheath slipped off and slid over the tip of the catheter exposing the back part of the electrode.

There was no patient injury. Procedure was completed before sheath moved. It is a single use device. The power setting point was 10 of cut and 0 of coag.

Device was returned to the MFR.

Manufacturer response (as per reporter) for Hook Electrode, Hook Electrode

They will investigate the issue.

Device:

Type: Bag, Hemodialysis, Continuous Renal Replacement Therapy
Manufacturer: Gambro Renal Products, Inc.
Lot #: 0921
Cat #: 6033765

Problem:
Urine collection bag split a hole in the middle and dumped nine liters of urine on the floor. Patient's daughter stated that this happened two other times over the weekend. The alarm to change the bag had just went off and the bedside RN was getting ready to do so when the bag exploded.

Device:

Type: Basket, Mechanical Lithotriptor, Stone Retrieval
Manufacturer: Olympus America
Brand: Lithocrush VMechanical Lithotriptor
Model #: BML-V442QR-30
Lot #: #93K

Problem:
The stone was captured in the basket. The handle was turned on to engage and crush the stone. The handle was turned and met with resistance. Upon further turning of the handle there was a loud snapping sound, where upon it was discovered that the rod that

manipulated the basket had broken distally near the handle. There were several attempts to disengage the stone. When that could not be accomplished, the sheath was removed leaving only the wires from the basket within the patient. The physician then attempted to push the wires forward to release the stone. The doctor attempted to pull the stone intact, but could not perform this due to the resistance of the impacted stone. It was then decided to withdraw the scope and consult a surgeon to remove the stone and basket via surgery. The broken instrument was put into a bag without reprocessing.

ORTHOPEDIC

Device:

Type: Ronguer, Disk
Manufacturer: Codman
Brand: Peapod
Cat #: 53-1255

Problem:
During a laminectomy, a pituitary ronguer was used but fell apart with use, due to the screw falling out. Screw not found in wound. X-ray confirmed.

CLINICAL CHEMISTRY

Device:

Type: Glucose Testing Strips
Manufacturer: Abbott Diabetic Care Inc.
Brand: Abbott Precision Pcx-plus
Lot #: 6CVK5G
Cat #: 80063-02

Problem:
Discovered our point of care glucose testing was varying by as much as 50% with our venous blood glucose testing. We did a study and proved with data that we had an average of 13% of our glucoses that varied by >20% between our point of care testing and venous testing. We then switched glucose testing strip lots and our variance was within expected variance <20%.

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Medical Device Problem Summaries

Summary of MedSun Reports Describing Adverse Events With IV Catheters

Intravenous (IV) catheters are common medical devices that are used for fluid and/or medication administration in the treatment of patients in all age groups. About 25 million Americans have intravenous catheters placed each year. IV catheters are placed in the veins of the upper or lower extremities, the larger veins of the neck, or the upper chest near the collar bone using a rigid, metal needle. The needle is removed and the plastic catheter, or cannula, remains in the vein. [1]

Over the past 2 years, MedSun has received 76 adverse event reports associated with the IV Catheter. The reports represent 6 manufacturers: Becton Dickinson (58), Smith Medical (9), B. Braun Medical, Inc. (6), Cook, Inc. (1), C.R. Bard, Inc. (1), and Unomedical A/S (1). The reports were submitted by 48 hospitals between July 2007 and July 2009. The most frequently reported device problems, in descending order of frequency, were:

- Needle did not retract properly
- Leak
- Piece broke off
- Insecure connection
- Tip broke off
- Hole in tubing
- Device component broke off
- Missing parts
- Needle bent

No reports involved a patient death. The patient injuries listed below were reported in 35 of these 76 reports.

- Needed to be re-stuck (17)
- Piece left, needed to be removed without surgery (6)
- Piece left, needed surgery to remove (4)
- Piece left in patient that was not removed (3)
- Nurse stuck by needle (3)
- Hematoma (2)

Of the reports that listed patient age, 11 had a patient age listed as less than 21 years and 35 had a patient age listed as greater than 21 years. Of the reports that listed patient gender, a total of 30 reports involved female patients and a total of 20 reports involved male patients.

These MedSun reports contributed to FDA awareness of the device problems. FDA currently has this issue under review.

Adverse Events

Device	Device identifiers (model , catalog number, lot)	Event Description
B. Braun medical/introcan safety 24 g x 3/4"	None/none/none	IV CATHETER REMOVED FROM HAND OF BABY AFTER IV INFILTRATED. AT REMOVAL, CATHETER TIP NOTED TO BE NOT INTACT. TIP WAS APPROXIMATELY HALF THE NORMAL LENGTH, TIP ANGLED, SMOOTH. X-RAY AND ULTRASOUND OF HAND DID NOT SHOW A RETAINED FOREIGN BODY.
Smiths medical md/acuvance plus	None/3350/37h235e03	NUCLEAR MEDICINE TECHNICIAN WAS REPOSITIONING THE ANGIOCATH AND THE CATHETER TIP SHEARED OFF. THE TECHNOLOGIST THINKS PART OF THE CATHETER BROKE IN THE PATIENT'S ARM. WHEN THE CATHETER WAS PULLED OUT, IT LOOKED LIKE SOME OF THE PLASTIC FROM THE CATHETER WAS MISSING. THE PATIENT WAS RETURNED TO ULTRASOUND THE NEXT DAY, AND AT THIS TIME THE SUPERFICIAL VEIN WAS FOUND TO BE THROMBOSED.
Smiths medical md/protectiv plus safety iv catheter	None/ref 3067/none	LEFT HAND IV SITE NEAR THUMB CHECKED AFTER GIVING MEDICATION. SITE COVERED WITH DRESSING. DRESSING REMOVED. CATHETER SLIGHTLY OUT OF VEIN AT INSERTION SITE. CATHETER BROKEN OFF WITH FOLLOW-UP X-RAY SHOWING A 1.6CM TUBULAR RADIOPAQUE DENSITY ADJACENT TO THE FIRST CARPOMETACARPAL JOINT FOREIGN BODY. FOLLOW-UP SURGICAL

		PROCEDURE TO REMOVE THE FOREIGN BODY IDENTIFIED IT AS AN IV CATHETER.
Becton dickinson/insyte autoguard winged	None/none/none	END CONNECTOR WOULD NOT CONNECT TO SYRINGE OR IV TUBING. ADDITIONAL INFO. OBTAINED FROM THE SITE: NO PRODUCT NUMBER IS AVAILABLE BECAUSE THE PACKAGING FOR THE PRODUCT WAS ALREADY DISCARDED WHEN THE NURSE REPORTED IT. THE INFANT HAD TO BE RESTUCK. THERE WAS NO DAMAGED PART. THE END OF THE IV WHERE A SYRINGE OR IV TUBING ATTACHES WOULD NOT ALLOW FOR ANYTHING TO SCREW ON.
Smiths medical md/protectiv	None/3048 /35e10se02	PATIENT HAD A 14 GAUGE IV CATHETER INSERTED IN THE ED. AFTER THE PATIENT ARRIVED IN THE UNIT, NURSING WAS PUSHING IV MEDICINES AND THE PATIENT COMPLAINED OF PAIN AND BURNING AT SITE. THE IV PUSH WAS IMMEDIATELY STOPPED AND THE SITE WAS INSPECTED. THE SITE APPEARED TO HAVE INFILTRATED. THE IV CATHETER WAS REMOVED AND IT WAS NOTICED THAT THE CATHETER HAD A CREASE AND A PIN POINT HOLE AT ONE EDGE. THE CATHETER HAD BEEN INSERTED IN THE BEND OF THE ELBOW AND IT IS BELIEVED THAT THE PATIENT BENT THEIR ELBOW BENDING THE CATHETER WHICH CAUSED THE CREASE. AFTER BENDING SEVERAL TIMES IT MADE A HOLE IN THE CATHETER.
Cook,/none	None/c-utlmy-7013-rsc-	THIS REPORT IS TO NOTIFY THE

	abrm-hc-fst-r /1859855	FDA OF LABELING CHANGES BY COOK ON THEIR 7 FR TRI-LUMEN CATHETERS, WHICH WE BELIEVE IS INTRODUCING THE POSSIBILITY OF A HUMAN ERROR AS THE ORIGINAL COLOR CODING IS BEING CHANGED BETWEEN THE DISTAL AND PROXIMAL CONNECTIONS OF THE CATHETER.
Becton dickinson infusion therapy systems/insyte autoguard	None/none/8284277	RN WAS STARTING AN IV ON ED PATIENT WHEN THE IV CATHETER NEEDLE SEPARATED FROM THE PLASTIC HUB. THE NEEDLE WAS RETRIEVED INTACT WITHOUT HARM TO THE PATIENT.
Becton dickinson infusion therapy systems/bd insyte autoguard	18 ga 1.16 in, 1.3 x 30mm/ref 381444/7340858	NURSE WAS ATTEMPTING TO PLACE AN 18 GAUGE INTRAVENOUS CATHETER (IV START) INTO A LABOR & DELIVERY PATIENT'S VEIN IN LEFT FOREARM. NURSE ENTERED THE PATIENT'S VEIN WITH THE CATHETER AND WHEN ATTEMPTING TO ADVANCE THE CATHETER, THE HUB BROKE OFF FROM THE PLASTIC ANGIO. FORTUNATELY THE NURSE WAS ABLE TO REMOVE THE CATHETER. POTENTIAL FOR DETACHED CATHETER TO HAVE ENTERED PATIENT'S VEIN.
B. Braun medical/introcan iv	None/none? 8c28258271	RN HAD A NEEDLESTICK AFTER PLACING AN 18 GAUGE IV CATHETER INTO A PATIENT. THE SAFETY ON THE CATHETER MALFUNCTIONED AND THE NEEDLE TIP WAS EXPOSED WHICH STUCK THE NURSE. MANUFACTURER RESPONSE FOR 18 GAUGE CATHETER, INTROCAN IV. CONTACTED

		BBRAUN REP ANDREA KU WHO RESPONDED THAT THEY WILL SEND INSTRUCTIONS REGARDING SHIPPING THE DEVICE AND SAMPLES FROM THE LOT # TO THIER QA DEPARTMENT.
Becton dickinson infusion therapy systems/angiocath	381523/none/none	THE PATIENT HAD A PERIPHERAL IV IN THEIR LEFT ANTERIOR FOREARM. THEY RECEIVED A METHAMPHETAMINE INFUSION OVER A TWO MINUTE PERIOD. UPON COMPLETION OF THE METHAMPHETAMINE INFUSION, NORMAL SALINE BEGAN INFUSING AT 100 CC/HR. AT THIS TIME, THE PATIENT COMPLAINED OF SOME DISCOMFORT AT THE IV SITE. THE IV WAS STOPPED AFTER ONLY 5 CC HAD INFUSED AND THE PHYSICIAN WAS INFORMED. THE NURSE REMOVED THE CANNULA SHORTLY AFTERWARDS AND AT THIS TIME IT WAS NOTICED THAT THE CANNULA TIP WAS ONLY ABOUT 1/4 INCH LONG WHEN IT SHOULD HAVE BEEN ONE INCH LONG. AFTER PALPATING BELOW THE IV INSERTION SITE, THE REMAINDER OF THE CANNULA SITE WAS IDENTIFIED AND FOUND TO STILL BE IN THE PATIENT. THE PATIENT WAS MADE AWARE OF SITUATION AND ENCOURAGED TO REMAIN ON BED REST, AND A LOOSE TOURNIQUET WAS APPLIED TO THE UPPER ARM. EXCISION OF CATHETER FROM THE LEFT FOREARM WAS PERFORMED AT THE BEDSIDE UNDER ULTRASOUND GUIDANCE.

Becton dickinson infusion therapy systems/insyte autoguard winged shielded	20ga/none/none	WHILE PLACING PERIPHERAL IV IN PATIENT'S ARM, NURSE CANNULATED THE VEIN WITH THE 20G ANGIOCATH. NURSE PRESSED THE BUTTON TO RETRACT THE NEEDLE AND LEAVE THE CATHETER IN THE VEIN. WHEN NURSE PULLED OUT THE NEEDLE, IT HAD ONLY HALF RETRACTED INTO THE SPRING MECHANISM AND WAS STICKING OUT AT AN ANGLE.
Becton dickinson infusion therapy systems/bd insyte autoguard	None/381444/8284277	UPON ADVANCING CATHETER, SHEATH SEPARATED FROM GREEN PLASTIC HUB, SHEATH REMOVED INTACT. NO PATIENT HARM.
Becton dickinson/insyte autogaurd	None/none/none	THE NURSE WAS ATTEMPTING TO INSERT A 22 GAUGE CATHETER INTO THE RIGHT ANTECUBITAL AREA. WHEN SHE WENT TO PULL THE CATHETER OUT, SHE NOTICED THAT PART OF THE CATHETER WAS MISSING. IT SEEMED TO HAVE BROKEN OFF INSIDE THE PATIENT'S ARM. THE NURSE DENIED REINSERTING THE NEEDLE BACK IN THE CATHETER ONCE SHE PULLED IT OUT. THE EMERGENCY DEPARTMENT PHYSICIAN WAS IMMEDIATELY NOTIFIED.
Becton dickinson infusion therapy systems/bd insyte autoguard	None/none/none	IV CATHETER INSERTED WITHOUT PROBLEM, GOOD BLOOD FLUSH BACK, NORMAL SALINE FLUSH, WHILE FLUSHING HUB OF CATHETER CRACKED AND UNABLE TO USE. REMOVED AND RETAINED.
Smiths medical asd/18g 1-1/4"cathlon	Cath iv 18g 1.75in radopqgrn/405420/07.01 535	RN STARTED 18 GAUGE IV AND HOOKED UP TUBING/FLUID. IV WAS LEAKING AT THE HUB. NEW IV STARTED WITH ANOTHER 18 GAUGE CATHETER

		WHICH ALSO LEAKED AT THE HUB. BOTH IVS DISCONTINUED AND A NEW IV WAS STARTED WITH A 16 GAUGE CATHETER. NO FURTHER LEAKAGE NOTED.
Becton dickinson infusion therapy systems/angiocath-n, autoguard	None/381720/8009372	RN IN PEDIATRIC ICU REPORTED A PROBLEM WITH THE BD ANGIOCATH-N AUTOGUARD. STATED THAT WHEN SHE WAS ATTEMPTING TO RESTART IV, THE ANGIOCATH INSERTED AND THE SPRING WOULDN'T WORK AND NEEDLE WOULDN'T RETRACT. ALSO HAD DIFFICULTIES WITH THE ANGIOCATH "SPLITTING" AND THE TIP "SHREDDING".
Becton dickinson infusion therapy systems/bd insyte autoguard	None/381423/none	MED SURG TECH WAS DISCONTINUING INTRAVENOUS ACCESS RESEAL FROM PATIENTS RIGHT ARM, IT WAS NOTED THAT THE HUB WAS LYING ON TOP OF THE SKIN AND WAS NOT CONNECTED TO THE CLEAR CATHETER PIECE NORMALLY INSERTED INTO THE VEIN. TECH IMMEDIATELY NOTIFIED PRIMARY RN WHO ASSESSED THE PATIENT, AND SEARCHED THE DRESSING, BED LINENS AND ENTIRE PATIENT ROOM FOR MISSING CATHETER. DILIGENT EFFORTS TO FIND CATHETER PIECE BY NURSE WERE UNSUCCESSFUL. PRIMARY PHYSICIAN WAS NOTIFIED AND SOFT TISSUE X RAY ORDERED.
Becton dickinson infusion therapy systems/insyte autoguard	None/381444/none	SOFT TISSUE ULTRASOUND DONE AT ANOTHER FACILITY REVEALED 1.8CM X 0.25 CM TUBULAR STRUCTURE WITHIN THE SUBCUTANEOUS SOFT TISSUES ALONG THE ANTERIOR

		ASPECT OF THE LEFT DISTAL FOREARM MEDIALLY, SUSPICIOUS FOR FOREIGN OBJECT. THIS WAS THE SITE OF A PREVIOUS IV. REQUIRED OUTPATIENT REMOVAL UNDER LOCAL ANESTHESIA.
B. Braun medical/introcan safety	None/4251644-02/9b12258302	THE SAFETY NEEDLE COVER WAS NOT PRESENT WHEN THE NEEDLE WAS REMOVED FROM THE ANGIOCATH AFTER INSERTION. NURSE EXAMINED CLOSELY FOR SIGNS OF THE CAP AND FOUND NONE. X-RAY TO PATIENT'S FOREARM REVEALED NO FOREIGN OBJECT FOUND.
Becton dickinson/insyte autoguard	None/381434 /7324911	WHILE INSERTING THE IV, NURSE FELT SOME RESISTANCE AND REMOVED THE ANGIOCATH. IT WAS NOTICED THAT THE ANGIO TIP HAD SHEARED.
Becton dickinson/insyte autoguard	None/381444 /7519078	THE IV CATHETER LEAKED WHEN FLUIDS/MEDICATIONS WERE PUSHED THROUGH. THE LEAK OCCURRED AT THE JOINT OF THE CATHETER AND THE GREEN PLASTIC. THE NURSE VERIFIED THAT THE MALE ADAPTER WAS TIGHT.
Becton dickinson infusion therapy systems/insyte autoguard	None/none/7088198	THE NURSE WAS PREPARING TO START AN IV LINE ON A PATIENT. SHE OPENED THE IV CATHETER FROM THE PACKAGE AND GRASPED THE WHITE SHIELD TO REMOVE IT. HOWEVER, WHEN SHE TRIED TO REMOVE THE DEVICE, THE IV CATHETER AND THE HUB REMAINED INSIDE THE SHIELD. THE REMAINDER OF THE NEEDLE AND NEEDLE GUARD CAME OUT. STAFF RETRACTED THE NEEDLE AND DISPOSED OF

		IT IN THE SHARPS CONTAINER. WHEN EXAMINING THE WHITE SHIELD, IT APPEARED THAT THE HUB WAS CROOKED AND SHOVED UP AGAINST ONE WALL OF THE PACKAGING. STAFF OBTAINED ANOTHER IV CATHETER TO START THE IV LINE. THERE WAS NO HARM TO THE PATIENT OR STAFF AS A RESULT OF THIS EVENT.
Becton dickinson infusion therapy systems/insyte autoguard	None/none/7088198	THE NURSE WAS PREPARING TO START AN IV LINE ON A PATIENT. SHE OPENED THE IV CATHETER FROM THE PACKAGE AND GRASPED THE WHITE SHIELD TO REMOVE IT. HOWEVER, WHEN SHE TRIED TO REMOVE THE DEVICE, THE IV CATHETER AND THE HUB REMAINED INSIDE THE SHIELD. THE REMAINDER OF THE NEEDLE AND NEEDLE GUARD CAME OUT. STAFF RETRACTED THE NEEDLE AND DISPOSED OF IT IN THE SHARPS CONTAINER. WHEN EXAMINING THE WHITE SHIELD, IT APPEARED THAT THE HUB WAS CROOKED AND SHOVED UP AGAINST ONE WALL OF THE PACKAGING. STAFF OBTAINED ANOTHER IV CATHETER TO START THE IV LINE. THERE WAS NO HARM TO THE PATIENT OR STAFF AS A RESULT OF THIS EVENT.
Becton dickinson infusion therapy systems/insyte autoguard	None/none/7100852	THE NURSE WAS PREPARING TO START AN IV ON THE PATIENT. WHEN THE WHITE SHEATH FROM THE IV WAS REMOVED, THE NURSE NOTED THAT THE NEEDLE INSIDE THE CATHETER WAS BENT. SHE REMOVED THE HUB AND DISCARDED IT IN THE SHARPS CONTAINER. UPON

		VISUAL INSPECTION, THE NEEDLE WAS OBVIOUSLY BENT TO ONE SIDE. THE NEEDLE WAS RETRACTED INTO THE SAFETY SHEATH AND SAVED ALONG WITH THE PACKAGING. NO PATIENT OR STAFF MEMBERS WERE HARMED AS A RESULT OF THIS INCIDENT. PICTURES OF THE DEFECTIVE NEEDLE WERE TAKEN IN ADDITION TO THE SUBMISSION OF THIS REPORT.
Becton dickinson/insyte autoguard	20 gauge, 1.16 inches/none/8007782	THE NURSE WAS PREPARING TO START AN IV LINE. WHEN SHE OPENED THE 20 GAUGE, 1.16 INCHES INSYTE AUTOGUARD IV PACKAGE, SHE NOTED THAT THE NEEDLE HAD PIERCED THE IV CATHETER APPROXIMATELY 2MM FROM THE DISTAL END OF THE DEVICE. OF NOTE WAS THAT THE NEEDLE HAD NOT RETRACTED WHEN THE NURSE DISCOVERED THE PUNCTURE. ALL OTHER ELEMENTS OF THE IV CATHETER WERE INTACT, WHICH LEAD STAFF TO THE CONCLUSION THAT SOMETHING WENT WRONG DURING THE MANUFACTURING OF THE DEVICE. THE NURSE WAS NOT HARMED, AND NO PATIENT WAS INVOLVED IN THE EVENT. SEVERAL MORE PACKAGES WERE OPENED FROM THE SAME LOT; HOWEVER, STAFF COULD NOT FIND ANY OTHERS WITH THE SAME DEFECT. AFTER THE DEVICE WAS INSPECTED BY RISK MANAGEMENT AND PHOTOS OF THE DEVICE TAKEN, THE AUTO RETRACT BUTTON WAS ACCIDENTALLY TRIGGERED. ALL PORTIONS OF

		THE DEVICE ARE BEING RETURNED TO THE MANUFACTURER FOR INVESTIGATION/ANALYSIS; HOWEVER, THE NEEDLE IS NOW HOUSED IN THE SAFETY GUARD.
Becton dickinson/insyte autoguard	381444/none/none	THE RN WAS ATTEMPTING TO START AN IV LINE WITH AN 18G CATHETER IN THE PATIENT'S LEFT ANTECUBITAL SPACE. THE RN SAW A BLOOD RETURN, INDICATING THAT THE IV LINE WAS "IN." HOWEVER, WHEN SHE PUSHED THE BUTTON TO RETRACT THE NEEDLE, IT WOULD NOT RETRACT. AT THIS POINT, THE PATIENT BEGAN MOVING AND WOULD NOT HOLD STILL. THE IV BECAME DISLODGED AND THE PATIENT PUSHED THE RN'S HAND THAT WAS HOLDING THE UNRETRACTED IV NEEDLE INTO THE RN'S OTHER HAND. THE RN WAS STUCK IN HER THUMB WITH A DIRTY NEEDLE AS A RESULT. IT IS UNKNOWN WHY THE NEEDLE DID NOT RETRACT. AFTER THE DEVICE WAS REMOVED, THE NEEDLE STILL WOULD NOT RETRACT. STAFF DISPOSED OF THE NEEDLE AND THE PACKAGING. THE RN HAS FOLLOWED UP WITH EMPLOYEE HEALTH. PATIENT WAS NOT HARMED. MANUFACTURER RESPONSE FOR SHIELDED IV CATHETER, INSYTE AUTOGUARD THE MANUFACTURER'S QUALITY DEPARTMENT HAS BEEN INFORMED OF THE EVENT.
Becton dickinson infusion therapy	None/none/8340372	A NURSE REPORTED THAT THE NEEDLE FROM THE INSYTE

systems/bd insyte autoguard		AUTOGARD IV CATHETER WOULD NOT RETRACT WHEN SHE PUSHED THE RETRACT BUTTON. STAFF ON THE FLOOR REPORT THAT THEY HAVE EXPERIENCED THE SAME PROBLEM RECENTLY, ALTHOUGH THERE SEEM TO BE NO APPARENT DEFECTS AND NO COMMONALITIES BETWEEN THE EVENTS. IN THIS PARTICULAR EVENT, THE NURSE WAS UNABLE TO GET THE NEEDLE TO RETRACT INTO THE SAFETY COVER. THE IV WAS REMOVED AND ANOTHER WAS USED TO START THE LINE. OTHER STAFF IN THE UNIT REPORT THAT THEY HAVE NEEDED TO PUSH THE BUTTON SEVERAL TIMES IN ORDER TO GET THE NEEDLE TO RETRACT. NO STAFF MEMBER WAS INJURED IN THIS EVENT. THE PATIENT HAD TO BE STUCK TWICE IN ORDER TO ESTABLISH AN INTRAVENOUS LINE. STAFF DID NOT SAVE THE DEVICE FROM THIS EVENT. MANUFACTURER RESPONSE (AS PER REPORTER) FOR 22GA 1.00INCH 0.9X25MM IV CATHETER, BD INSYTE AUTOGUARD A COPY OF THIS REPORT HAS BEEN FAXED TO THE MANUFACTURER.
B. Braun medical/introcan safety	None/425 4512/4b 13258w12	AN INFANT WAS ADMITTED WITH A FEVER AND A URINARY TRACT INFECTION (UTI). THE NURSING STAFF WAS ATTEMPTING TO START AN IV WITH THE INTROCAN SAFETY CATHETER. THE IV CATHETER STARTED LEAKING AFTER BEING INSERTED. THE PATIENT HAD TO BE RE-STUCK WITH A

		NEW CATHETER.
Becton dickinson infusion therapy systems/insyte autoguard intravenous catheter (18 guage 1 1/4)	None/381444/8066658	THE PATIENT HAD AN INTRAVENOUS CATHETER PLACED IN PREPARTION FOR SURGERY. THE NURSE NOTICED THAT BLOOD WAS LEAKING FROM THE INTRAVENOUS CATHETER. UPON FURTHER INVESTIGATION, THE BLOOD WAS SQUIRTING OUT FROM A PIN HOLE BETWEEN THE INTRAVENOUS CATHETER AND HUB OF THE INTRAVENOUS CATHETER. THE INTRAVENOUS CATHETER WAS REMOVED AND ANOTHER INTRAVENOUS ACCESS WAS ESTABLISHED. ALL OF THE INTRAVENOUS CATHETERS FROM THAT LOT WERE REMOVED FROM ALL PATIENT CARE AREAS. THE MANUFACTURER WAS NOTIFIED AND WE ARE WAITNG TO HEAR FROM THEM.
Becton dickinson/bd insyte autoguard	None/none/7124877	NEWLY OPENED ANGIOCATH WAS NOTICED TO HAVE A BENT TIP.
Becton dickinson/shielded insyte autoguard	None/none/7305560	WHILE ATTEMPTING AN IV INSERTION, IT WAS NOTED THAT THE END OF THE PLASTIC CANNULA WAS CRACKED. THE TIP WAS IN ONE PIECE, BUT DID NOT ALLOW FOR SUCCESSFUL THREADING OF THE CANNULA.
Becton dickinson infusion therapy systems/bd insyte autoguard winged angiocath	8228654/381523 (22 gauge)/ 8254631, 8217913, 8191986	RETRACTABLE "SAFETY" BD INSYTE AUTOGUARD WINGED ANGIOCATHS ARE NOT RETRACTING. THE NURSE GOT NEEDLE STICK AS A RESULT OF THIS EVENT. MANUFACTURER RESPONSE FOR SAFETY ANGIOCATH, BD INSYTE AUTOGUARD WINGED ANGIOCATH BD LETTER DATED 3/17/09 RE SAMPLE - LOT

		8217913, CAT # 381523 EXCESSIVE AMOUNTS OF GEL WERE PLACED IN THE GRIP ASSEMBLIES DURING MANUFACTURING.
Becton dickinson/saf-t-intima	None/none/7150663	THE NURSE HAD SUCCESSFULLY INSERTED A PERIPHERAL IV. WHEN WITHDRAWING THE STYLET TO LEAVE THE PLASTIC ANGIO CATHETER IN PLACE, THE WIRE PART OF THE STYLET BROKE LEAVING THE NEEDLE AND PART OF THE WIRE WITHIN THE PLASTIC TUBING. WE HAVE NEVER SEEN THIS MALFUNCTION BEFORE. IV WAS REMOVED AND A NEW ONE WAS INSERTED. ORIGINAL PACKAGING WAS NOT SAVED BUT DEVICE WAS FROM ONE OF TWO LOT NUMBERS. THE DEVICE IS AVAILABLE TO BE PICKED UP BY A REPRESENTATIVE.
Becton dickinson infusion therapy systems/saf-t-intima	383323/none/7180035	NURSE INSERTED 22G SAF-T-INTIMA IV CATHETER AND WITHDREW THE STYLET. WHEN DEVICE WAS FLUSHED, IT LEAKED AT THE POINT WHERE THE CATHETER CONNECTS TO THE BUTTERFLY PORTION. DEVICE WAS REMOVED AND ANOTHER WAS SUCCESSFULLY INSERTED IN A NEW IV SITE. THIS IS THE SECOND OCCURRENCE OF THIS TYPE IN THE SAME DAY. BOTH DEVICES WERE FROM THE SAME LOT NUMBER BUT ONLY ONE DEVICE WAS SAVED. THE BD REP WILL BE NOTIFIED THAT THEY CAN PICK UP THE DEVICE FOR EXAMINATION.
Becton dickinson	381523/none/6200114	TECHNICIAN HAD INSERTED IV

infusion therapy systems/insyte autoguard winged		IN PREPARATION FOR A NUCLEAR MEDICINE SCAN. WHEN FLUSHING WITH NORMAL SALINE AFTER INSERTION, NOTED BLOODY FLUID LEAKING OUT OF IV DEVICE WHERE CATHETER ATTACHES TO HUB. IV REMOVED AND REPLACED WITH A NEW DEVICE.
Becton dickinson/bd nexiva closed iv catheter system	383505/none/7330139	NURSE SUCCESSFULLY INSERTED IV CATHETER, BUT WAS UNABLE TO REMOVE THE STYLET. REMOVED ENTIRE DEVICE AND HAD TO RESTICK THE PATIENT WITH A NEW IV CATHETER.
Becton dickinson infusion therapy systems/nexiva	None/none/none	IV CATHETER PLACED IN PATIENT'S BLOOD VESSEL; CATHETER WITH HOLE CAUSED BLEED. DEVICE REMOVED WITHOUT FURTHER INCIDENCE. NO PATIENT HARM.
Becton dickinson/insyte-n autoguard	24g 0.56 in; 0.7 x 14 mm/381411/none	IV ACCESS WAS ATTEMPTED WITH A BD INSYTE-N AUTOGUARD. THE NEEDLE WOULD NOT RETRACT FROM THE CATHETER WHEN THE BUTTON WAS PUSHED, DESPITE THE PHYSICIAN'S AND TWO NURSES ATTEMPTS. A SECOND SITE, USING A DIFFERENT TYPE NEEDLE WAS NECESSARY IN THIS INSTANCE.
Becton dickinson infusion therapy systems/bd nexiva	None/383531/6164579	A 24 GAUGE NEXIVA CATHETER FRACTURED AT THE HUB, LEAKING RESULTED. THE IV WAS REMOVED WITHOUT INCIDENT. SLIGHT RAISED DISCOLORED AREA AT SITE.
Becton dickinson infusion therapy systems/insyte autoguard	None/38144/8066658	MULTIPLE REPORTS FROM MATERNITY NURSING UNIT AND ANESTHESIA STAFF OF IV FLUID LEAKING FROM THE

		SAME SPOT, WHERE THE CATH TUBING MEETS THE GREEN HUB. ALL IDENTIFIED AS HAVING SAME LOT NUMBER. NO PATIENT INFORMATION PROVIDED. LOT PULLED IN ALL AREAS.
Becton dickinson infusion therapy systems/bd nexiva hf	20g 1.00 in 1.1x25mm/none/9043270	AFTER SUCCESSFUL VEIN CANNULATION, WHEN THE INSERTER ATTEMPTED TO REMOVE THE STYLET, THE INNER PEICE OF THE GREY CLIP THAT HOLDS THE NEEDLE COVER IN PLACE POPPED OFF. MANUFACTURER RESPONSE FOR CLOSED IV CATHETER SYSTEM, BD NEXIVA HF REQUESTED THAT THE DEVICES BE RETURNED FOR EVALUATION.
Becton dickinson infusion therapy systems/bd nexiva	18g 1.25 inches 1.3x32mm/none/8340308	FOLLOWING SUCCESSFUL CANNULATION OF THE VEIN, THE STYLET WAS REMOVED WITHOUT RESISTANCE. IMMEDIATELY BLOOD APPEARED IN THE WHITE SEPTUM WHERE THE NEEDLE IS REMOVED FROM THE CATHETER. THE IV HAD TO BE REMOVED AND A NEW ONE INSERTED. MANUFACTURER RESPONSE FOR CLOSED IV CATHETER SYSTEM, BD NEXIVA REQUESTED RETURN OF PRODUCT FOR EVALUATION. RETURNED ON DATE OF EVENT.
Becton dickinson infusion therapy systems/nexiva hf	None/383536/none	THE NURSE WAS UNABLE TO REMOVE THE STYLET FROM THE BD NEXIVA CLOSED IV CATHETER AFTER SUCCESSFUL INSERTION. THE CATHETER NEEDED TO BE REMOVED AND A NEW ONE WAS INSERTED.
Unomedical/insulfon	None/none/none	PATIENT WITH SEVERE

catheter		PROTEIN C DEFICIENCY, STATUS POST (S/P) PERINATAL STROKE, WHO HAS RESIDUAL DISABILITIES FROM THE STROKE AND REQUIRES LIFELONG ANTICOAGULATION TO PREVENT RECURRENCE. HER HOME ANTICOAGULATION IS SUPERVISED BY NURSE PRACTITIONER (NP) FOR THE ANTICOAGULATION SERVICE. THE DRUG IN USE FOR PROPHYLAXIS IS ENOXAPARIN ADMINISTERED SUBCUTANEOUSLY VIA INSUFLON CATHETER. NEW CATHETER WAS PLACED LAST WEEK BY MOTHER, WHO IS EXCEPTIONALLY COMPLIANT AND CAREFUL. LAST CATHETER PLACEMENT IN THE LEFT LOWER ABDOMEN RESULTED IN AN ABDOMINAL WALL HEMATOMA, FOR WHICH SHE WAS SEEN IN THE ED. ELECTED TO CONTINUE NECESSARY ANTICOAGULATION VIA OTHER SITES; THE BLEEDING WORSENED SUBSTANTIALLY REQUIRING ADMISSION TO THE ICP, AND RED CELL TRANSFUSION. THE DIAGNOSIS IS ABDOMINAL WALL (PROBABLY RECTUS SHEATH) BLEED, NO DOUBT RELATED IN PART TO THE INSUFLON PLACEMENT, AND IN PART TO THE REQUIREMENT FOR ANTICOAGULATION.
Becton dickinson infusion therapy systems/insyte autogaurd iv catheter (blue 22ga x 1.00in safety)	None/381423/8121957	WHILE STARTING A PERIPHERAL IV, THE NURSE NOTICED THAT THE FLUID WAS LEAKING FROM AROUND THE CONNECTION TO THE INSYTE HUB. THIS HAS HAPPENED AT

		LEAST ONE OTHER TIME RECENTLY TO ANOTHER NURSE. UPON INSPECTION OF THE RIM OF THE INSYTE, IT LOOKS AS IF THE LIP IS SLIGHTLY MELTED, NOT ALLOWING A TIGHT SEAL.
Becton dickinson/insyte autoguard needle	None/none/none	ACCESSED VEIN WITH 22GAUGE AUTOGUARD NEEDLE. AFTER WITHDRAWING NEEDLE FROM CATHETER, NEEDLE DID NOT RETRACT IMMEDIATELY WHEN THE BUTTON WAS PUSHED. NEEDLE WAS SLUGGISH TO RETRACT. I HAD TO WAIT, HOLDING THE IV ACCESS IN MY LEFT HAND FOR NEEDLE TO RETRACT WHILE HOLDING THE NEEDLE IN THE RIGHT HAND.
Becton dickinson/insyte autoguard	None/381423/8297571	INSYTE AUTO GUARD NEEDLE IS NOT RETRACTING DURING PERIPHERAL IV INSERTION.
Becton dickinson/insyte autoguard	None/381423/8297571	BD INSYTE AUTOGUARD 22G NEEDLE IS NOT RETRACTING DURING PERIPHERAL IV INSERTION.
Becton dickinson/insyte autoguard	None/381434/8274614	SAFETY DEVICE ON INSYTE DID NOT WORK-NEEDLE DID NOT RETRACT WHEN BUTTON WAS PUSHED.
Becton dickinson/insyte-autoguard- shielded iv catheter	None/381423/8297571	NURSE PUSHED THE RETRACTION BUTTON AND IT STUCK DOWN WITHOUT RETRACTING THE NEEDLE. NURSE PUSHED THE NEEDLE AGAINST A HARD SURFACE AND THEN IT RETRACTED.
Becton dickinson/insyte autoguard	None/none/none	IV ACCESSED BY 18 GAUGE NEEDLE. UPON REMOVAL OF NEEDLE BY ACTIVATING SAFETY DEVICE, THE CATHETER BECAME DISLODGED FROM THE HUB AND NEEDED TO BE RETRIEVED

		FROM PATIENT'S VEIN. THE CASE WAS REVIEWED LOOKING FOR TECHNIQUE. NURSE USED THE CORRECT TECHNIQUE. THEREFORE THE CAUSE WAS THOUGHT TO BE RELATED TO FAULTY CATHETER AT HUB.
Becton dickinson infusion therapy systems/bd insyte autoguard	Ref 381434/8009353, h33118-3 a(8-06)/ 7116673	RN WAS STARTING IV FOR PATIENT GOING TO SURGERY. CANNULA BROKE OFF BETWEEN PLASTIC CANNULA AND HUB.
Becton dickinson/bd insyte autoguard	H3116-3/ref 381423/7122242	WHEN TRYING TO RESTART AN IV ON A PATIENT THE NURSE PUSHED THE WHITE BUTTON TO RETRACT THE NEEDLE AND NOTICED THAT THE NEEDLE WAS STILL ABOVE THE SHIELD (ALMOST 1 INCH).
B. Braun medical/introcan safety	None/none/none	PATIENT WAS ADMITTED TO THE HOSPITAL TO RULE OUT SEPSIS. HIS HOSPITAL COURSE WAS UNCOMPLICATED. HIS BLOOD CULTURES, CEREBROSPINAL FLUID CULTURE, AND URINE CULTURE WERE ALL NEGATIVE. WHILE PREPARING PATIENT FOR DISCHARGE TO HOME, THE INTRAVENOUS (IV) ACCESS WAS DISCONTINUED, HOWEVER WHEN IT WAS DISCONTINUED A PIECE OF THE IV CATHETER BROKE OFF AND STAYED WITHIN THE VEIN OF THE SCALP. SURGERY WAS ALERTED AND EVALUATED THE PATIENT. IT WAS DETERMINED THAT THE CATHETER COULD NOT BE REMOVED AND THE PATIENT WAS SCHEDULED FOR SURGERY. A CT SCAN LOCALIZATION IDENTIFIED THE CATHETER AND THE

		SURGEON WAS ABLE TO REMOVE THE TIP OF THE CATHETER UNDER GENERAL ANESTHESIA. BECAUSE THE PATIENT WAS PLACED UNDER GENERAL ANESTHESIA, HE WAS KEPT OVERNIGHT FOR OBSERVATION. THE PATIENT WAS DISCHARGED HOME IN A STABLE CONDITION. THE PRODUCT WAS RETAINED BY RISK MANAGEMENT; HOWEVER NO PRODUCT INFORMATION WAS AVAILABLE.
Smiths medical asd/acuvance safety i.v. catheters	24g safety catheter/335304/none	PATIENT HAD 24G ACUVANCE IV INSERTED DURING THE MORNING HOURS. DURING THE EVENING HOURS, WHILE THE PATIENT WAS BEING HELD BY HIS PARENT, IT WAS NOTED THAT IV TUBING CAME APART AT THE HUB AND BLOOD WAS LEAKING OUT. IV DID NOT HAVE TO BE REPLACED AND NO PATIENT HARM WAS NOTED.
Becton dickinson infusion therapy systems/bd insyte autoguard venous catheter - 18 ga 1.16in	None/none/8284277	LABORING PT - STARTING IV AND CATHETER BROKE OFF AT THE HUB AND WAS RETAINED IN PATIENT'S ARM. PT WAS BEING INDUCED SO WAS BEING ALLOWED TO LABOR AND DELIVER AND THEN CATHETER WOULD BE REMOVED BY STAFF VASCULAR SURGEON.
Becton dickinson infusion therapy systems/insyte autoguard	None/8134797/none	NEEDLE RETRACTED AND COULD NOT THREAD CATHETER, PATIENT REQUIRED RESTICK.
Smiths medical md/jelco protectiv plus safety	None/3060/38b27sc05	A 22G ANGIOCATH WAS EASILY INSERTED INTO THE PATIENT'S RIGHT FOREARM; HOWEVER, THE ANGIOCATH WOULD NOT FLUSH. WHEN AN ATTEMPT WAS MADE TO REMOVE THE

		ANGIOCATH, THERE WAS SOME RESISTANCE. WHEN THE CATHETER WAS REMOVED IT WAS NOT INTACT. THE MD WAS NOTIFIED AND AN X-RAY WAS ORDERED. THE SHEARED PORTION OF THE CATHETER WAS FOUND TO BE SUBCUTANEOUS AND WAS NOT REMOVED. THE REMAINDER OF THE CATHETER WAS SAVED AND WILL BE RETURNED TO THE MANUFACTURER UPON REQUEST.
Becton dickinson/bd insyte autoguard	None/none/7348099	AN 18 GAUGE INSYTE AUTOGUARD WAS BEING INSERTED INTO THE PATIENT'S ARM. WHEN THEN THE RETRACTION WAS DEPLOYED USING THE PUSH BUTTON, THE GREEN HUB OF THE IV WAS SEEN DANGLING FROM THE PATIENT'S ARM/INSERTION SITE. THE CATHETER WAS "MISSING." THE CATHETER COULD NOT BE LOCATED AT FIRST. THE PATIENT WAS X-RAYED AND THE CATHETER WAS NOT LOCATED. THE BD REPRESENTATIVE CAME OUT AND WAS ABLE TO SEE WITH MICROSCOPIC LENSES THAT THE CATHETER HAD ACTUALLY RETRACTED BACK INTO THE RETRACTION DEVICE OF THE IV.
Becton dickinson infusion therapy systems/bd insyte autoguard	None/none/7340858	AN 18 GAUGE 1.16 INCH IV CATHETER BEING INSERTED TO LEFT WRIST, NURSE WENT TO ADVANCE CATHETER AND NOTED CATHETER NO LONGER ATTACHED TO HUB. CATHETER APPEARS TO BE IN RETRACTION CHAMBER. MANUFACTURER RESPONSE

		FOR 18 GAUGE SHIELDED IV CATHETER, BD INSYTE AUTOGUARD LOCAL REPRESENTATIVE AVAILABLE ON SITE TO EXAMINE CATHETER.
Becton dickinson/bd instye autoguard	None/none/7352356	STAFF MEMBER ATTEMPTED TO INSERT AN 18 GAUGE IV CATHETER INTO LEFT FOREARM. THE CATHETER PUNCTURED THE SKIN, BUT THEY WERE UNABLE TO ADVANCE THE CATHETER. AFTER THE CATHETER WAS REMOVED, IT WAS NOTED THAT THE TIP OF THE CATHETER WAS MISSHAPED, AND APPEARED TO BE DEFECTIVE.
Becton dickinson/intima	None/none/7215265	AFTER CANNULATING THE VEIN AND THE NEEDLE WAS REMOVED, WHILE FLUSHING THE CATHETER, I NOTICED THAT THERE WAS A HOLE IN THE TUBING AT THE HUB WHERE THE HUB AND THE TUBING MEET.
Becton dickinson infusion therapy systems/bd insyte autoguard shielded iv catheter	None/381544/8011121	FLASH OF BLOOD OBSERVED IN HUB UPON INSERTION. ENTIRE NEEDLE ADVANCED. AT THAT TIME IT WAS NOTED THAT NO PLASTIC CATHETER WAS ATTACHED TO THE GREEN HUB. CATHETER WAS NOT IN THE PACKAGE AND WAS MISSING ENTIRELY.
B. Braun medical/introcan safety	None/4252560-02/7l22258248, 7k02258n27	THE IV WAS STARTED WITH AN 18 G CATHETER. THE NURSE VERBALIZED THAT THE IV CATHETER WAS INSERTED WITHOUT DIFFICULTY AFTER APPROPRIATE SKIN PREP. SHE NOTED THAT THE PATIENT HAD "GOOD" VEINS AND THAT THEY WERE LARGE AND THAT SHE

		HAD NO PROBLEMS AT ALL. THE PATIENT RECEIVED 4MG MORPHINE THROUGH THE IV 20 MINUTES LATER. THE PATIENT ALSO HAD A CT DONE 40 MINUTES AFTER THE IV WAS STARTED. THE NURSE DID NOT NOTICE ANY REDNESS OR SWELLING OR ANY SIGNS OF INFILTRATION AND ADMINISTERED THE MORPHINE WITHOUT DIFFICULTY. PATIENT DID NOT HAVE ANY COMPLAINTS OF PAIN IN THE RIGHT ARM OR AT THE INSERTION SITE. THE IV WAS REMOVED BY ANOTHER NURSE 2 HOURS AFTER PLACEMENT. IT WAS NOTED TO BE "BROKEN OFF" AT THAT TIME AND DOCUMENTED. TWO PHYSICIANS WERE THEN NOTIFIED FOR FURTHER EVALUATION. THE NURSE WHO STARTED THE IV WAS SPECIFICALLY ASKED IF SHE HAD SLID THE NEEDLE PORTION IN AND OUT OF THE CATHETER PORTION AT ALL. SHE SAID THAT SHE DID NOT, AND STATED THAT SHE KNEW THIS WAS SOMETHING THAT SHOULD NOT BE DONE. AFTER THE FRACTURED CATHETER WAS DISCOVERED AN X-RAY WAS DONE THAT CONFIRMED A RETAINED PORTION OF CATHETER. A PARTIAL CUT DOWN WAS PERFORMED IN THE OR UNDER LOCAL ANESTHESIA AND NO FOREIGN BODIES WERE FOUND. FOLLOWING THE OR, A CHEST X-RAY AND CHEST CT SCAN WERE DONE AND THE CATHETER WAS NOT FOUND IN THE LUNGS OR CHEST.

		CONSULTS WITH RADIOLOGY, VASCULAR SURGERY, CHEST SURGERY, PEDIATRICS, AND ANESTHESIA FOLLOWED.
Becton dickinson infusion therapy systems/insyte autoguard	B-d 18 guage insyte autoguard/none/none	NURSE WAS DISCONTINUING THE CATHETER FOLLOWING AN INTERMITTENT INFUSION. SHE REMOVED THE TAPE AND STATLOCK. WHEN PULLING ON THE ULTRASITE ADAPTER AND THE HUB, IT SEPARATED FROM THE ACTUAL CATHETER. NURSE WAS ABLE TO REMOVE THE CATHETER IN ITS ENTIRETY WITH HER FINGERS.
Becton dickinson/insyte autoguard	Ref381444/none/7352356	RN WAS INSERTING #18 ANGIOCATH. WHEN THE WHITE BUTTON WAS RELEASED FOR RETRACTION OF THE NEEDLE, BLOOD FLEW INTO THE BOTTOM OF THE PLASTIC CONTAINER AND SQUIRTED OUT OF THE HOLE IN THE BOTTOM OF THE PLASTIC CONTAINER.
Becton dickinson infusion therapy systems/bd insyte autoguard winged 24ga 0.75 in	None/ref 381512/none	NURSE PREPARING TO PLACE AN INTRAVENOUS CATHETER IN THE PATIENT AND WHEN THE NURSE OPENED THE BD 0.75 INCH IV NEEDLE, THE PLASTIC CATHETER FELL OFF THE NEEDLE HUB. THE NEEDLE ITSELF HAD ALREADY BEEN RETRACTED INTO THE HUB AND WAS BENT BEFORE THE STERILE PACKAGE WAS OPENED. ANOTHER INTRAVENOUS CATHETER WAS USED TO PLACE THE IV IN THE PT.
Smiths medical md/protectiv	3050/none/none	WHILE INSERTING A PIV 22 GAUGE CATHETER, RN WAS UNABLE TO RETRACT THE NEEDLE AFTER RECEIVING A BLOOD RETURN.

Smiths medical md/protect iv safety iv catheter	None/none/37k30sc06	IV CATHETER WAS BEING INSERTED AND IT HIT A VALVE. NURSE WITHDREW CATHETER AND NOTICED IT TO BE SHORTER THAN NORMAL. THE END OF (20 GAUGE) CATHETER WAS MISSING WITH ROUGH EDGE.
Smiths medical md/20gx1" protectiv plus safety i.v. catheter radiopaque	3067/none/none	THE NURSE HAD INSERTED A NUMBER 20 GAUGE CATHETER INTO THE PATIENT'S ARM. THE NEEDLE WAS RETRACTED AND THE CATHETER WAS FOUND LEAKING AROUND THE HUB. WHILE FLUSHING TO CHECK FOR PATENCY, IT WAS NOTED THAT SALINE WAS COMING OUT FROM AROUND THE HUB OF THE CATHETER. UPON INSPECTION OF THE HUB, IT WAS FOUND TO BE BROKEN. NO INJURY TO THE PATIENT.
Becton dickinson infusion therapy systems/intravenous catheter 18 gauge	381444/8009355 h3120-3 a(8-06)/ 7291865, 72412787, or 7144153	WHILE PREPARING THE PATIENT FOR DISCHARGE FROM OUTPATIENT SURGERY, THE NURSE REMOVED THE IV SITE DRESSING THAT SECURED AN 18 GAUGE ANGIO CATHETER. AS SHE REMOVED DRESSING, THE HUB OF THE CATHETER FELL TO THE FLOOR WHILE APPROXIMATELY 1 INCH OF THE CATHETER REMAINED IN THE PATIENT'S LEFT ARM. THE RETAINED CATHETER WAS REMOVED UNDER FLUOROSCOPY. UPON INSPECTION OF THE BROKEN CATHETER IT APPEARED TO BE A COMPLETE, CLEAN BREAK WITH NO JAGGED EDGES, BENDS OR SHEARING.
Becton dickinson/bd insyte autoguard	381434/381434/7200338	RN STARTED AN IV ON THE PATIENT. THE IV WENT IN EASILY UNTIL THE RN TRIED

		TO THREAD THE LAST 1/4 INCH OF THE CATHETER. THE RN THEN NOTICED THAT BLOOD WAS LEAKING OUT OF THE END OF THE CATHETER CLOSEST TO THE PINK HUB. RN REALIZED THE CATHETER WAS DEFECTIVE AND TRIED TO RETRACT THE NEEDLE. THE NEEDLE WOULD NOT RETRACT. RN GRABBED THE END OF THE PINK HUB AND IT PULLED AWAY FROM THE PATIENT WITHOUT THE CATHETER. RN WAS ABLE TO GRAB THE END OF THE CATHETER AND PULL IT OUT BEFORE IT MIGRATED INTO THE VEIN. RN NOTICED THAT THE CATHETER NEAREST THE PINK HUB HAD A LARGE HOLE IN IT.
C.r. bard inc., bard electrophysiology division/ssv	None/808700/s25589	THERE WERE TWO EVENTS REPORTED WITH THE SAME ISSUE. THE NEEDLE WHICH CAME WITH THE SSV KIT WOULD NOT ACCEPT ANY WIRE (2 WIRES ATTEMPTED). THE NURSE HAD TO RESTICK THE PATIENT WITH ANOTHER NEEDLE. THREE DAYS LATER, THE GUIDEWIRE THAT CAME WITH THE SHEATH WOULD NOT PASS THROUGH THE ACCESS NEEDLE THAT CAME WITH THE SHEATH. AGAIN, THE PATIENT REQUIRED A SECOND ACCESS STICK WITH A NEW NEEDLE. NEITHER PATIENT WAS HARMED, BUT THE ENTIRE LOT WAS PULLED FROM THE SHELF AND RETURNED TO THE MANUFACTURER.
Becton dickinson/insyte, autoguard	None/none/7345737	THE CATHETER WAS BEING INSERTED INTO A PATIENT FOR RADIOLOGY TESTS; THE

		CATHETER IS INTRODUCED WITH THE NEEDLE, WHICH IS THEN WITHDRAWN (BY A SPRING MECHANISM IN THE SYRINGE) WHILE THE CATHETER STAYS IN PLACE. WHEN THE SYRINGE WAS WITHDRAWN, THE HUB WAS DETACHED FROM THE CATHETER. THE CATHETER WAS FOUND TO HAVE NOT DETACHED FROM THE NEEDLE, AS IT WAS SUPPOSED TO; AND IT WAS FOUND IN THE SYRINGE. SINCE IT DETACHED FROM THE HUB, THE CATHETER COULD HAVE EMBOLIZED IN THE PATIENT HAD IT NOT BEEN WITHDRAWN BACK INTO THE SYRINGE. IN THIS EVENT THE PATIENT WAS NOT INJURED, BUT REQUIRED AN ADDITIONAL NEEDLE STICK.
Becton dickinson infusion therapy systems/insyte autoguard	20 gauge/none/8039726	THE PATIENT WAS IN THE POST-ANESTHESIA RECOVERY UNIT, WHEN THEY LIFTED THEIR HAND AND A SNAP WAS HEARD. THE IV WAS NOTED TO BE LEAKING AND WAS CRACKED AT THE HUB. IV ADMINISTRATION WAS DISCONTINUED, AND THE PATIENT WAS NOT HARMED AS A RESULT OF THIS INCIDENT.
Becton dickinson/bd insyte autoguard	20 ga 1.00in/ref 381433/8116575	WHEN INSERTED INTO THE PATIENT'S VEIN, THE CATHETER DID NOT SLIDE OFF THE NEEDLE AS EXPECTED, SO IT DID NOT SEAT PROPERLY IN THE VEIN. THE NEEDLE RETRACTED AS EXPECTED, BUT THE CATHETER DID NOT ADVANCE, AND HAD TO BE REPLACED. PATIENT WAS NOT HARMED, BUT HAD AN

		ADDITIONAL VENIPUNCTURE AS A RESULT. WE HAVE HAD 3 PRIOR INSTANCES OF CATHETERS NOT WORKING PROPERLY, AND HAVE PULLED ALL DEVICES OF THIS LOT # AND ARE REQUESTING REPLACEMENT PRODUCT.
Becton dickinson infusion therapy systems/bd insyte autoguard winged	None/none/none	AN #18 INSYTE CATHETER WAS BEING INSERTED IN THE RIGHT FOREARM OF A PT. WHILE A STRIP OF TAPE WAS BEING PLACED UNDER THE CATHETER HUB TO STABILIZE THE SITE, THE TAPE STUCK TO THE RN'S GLOVE AND IV CATHETER AND HUB TURNED TO THE LEFT 90 DEGREES. RN STRAIGHTENED THE HUB AND CATHETER NOTICING AT THE SAME TIME THAT A SMALL HEMATOMA STARTED TO DEVELOP. TAPE WAS APPLIED OVER THE HEMATOMA AND THE WINGS OF THE HUB WERE TAPED DOWN. THE METAL NEEDLE WAS RETRACTED WITH NO BLOOD RETURN. A SALINE SYRINGE WAS ATTACHED TO THE HUB TO FLUSH THE CATHETER. AT THAT TIME, SALINE SQUIRTED AROUND THE HUB. THE SYRINGE WAS TIGHTENED AND SALINE WAS FLUSHED A SECOND TIME. SALINE AGAIN SQUIRTED AROUND THE HUB. THE TAPE WAS REMOVED FROM THE IV SITE OVER THE WINGS OF THE CATHETER AND OVER THE SITE OF THE HEMATOMA. ON REMOVING THE CATHETER WITH THE SALINE SYRINGE ATTACHED, THE HUB ONLY WAS WITHDRAWN. IMMEDIATE PRESSURE WAS APPLIED TO

		THE VEIN AND THE ER MD WAS CALLED TO THE BEDSIDE. MD PALPATED THE VEIN WITH NO CATHETER FELT. X-RAYS DONE ON THE FOREARM, HUMERUS, AND CHEST AS WELL AS A CT SCAN W/O CONTRAST. RESULTS WERE INCONCLUSIVE. EVENT DISCLOSED TO PATIENT AND FAMILY. HEALTHCARE PROFESSIONAL IMPRESSION: IT APPEARS THAT THERE MIGHT HAVE BEEN A FLAW IN THE CATHETER IN THAT THE METAL PIECE IN THE HUB WAS MISSING. THIS COULD HAVE ALLOWED FOR CATHETER DISPLACEMENT.

Additional Information:

[1] University of Cincinnati, The Ohio State University, and Case Western Reserve University. Anesthesia: Intravenous Catheter Complications. NetWellness Consumer Health Information. Last reviewed June 18, 2007, by Gareth S. Kantor, M.D. http://www.netwellness.org/healthtopics/anesthesiology/ivcomplications.cfm[24]

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Summary of MedSun Reports Describing Adverse Events With Patient-Controlled Analgesia (PCA) Pumps

Print Item
E–mail Item

A patient-controlled analgesia (PCA) pump is a computerized machine that is attached to a patient's intravenous (I.V.) line. A patient can choose when to take more pain medicine through the use of the PCA pump. The machine contains a syringe of pain medicine as prescribed by a doctor. The syringe is attached to tubing and connected directly to the I.V. line. In some cases, the pump is set to deliver a small, constant flow of pain medicine. When a patient feels pain, he or she can press the button on the pump for additional pain medicine. The machines have built-in safety features. The total amount of analgesic (pain reliever) that the patient can self-administer is within a safe limit [1]. Over the past 2 years, MedSun has received 17 adverse event reports associated with the PCA pumps that resulted in either over-infusion or under-infusion of the drug to the patient. These reports include devices manufactured by the following manufacturers: Hospira LTD (6), Baxter Healthcare Corporation (4), Sistemas Medicos Alaris (2), B. Braun Medical, Inc. (1), Cardinal Health (1), Curlin Medical (1), , IRadimed Corporation

(1), and Smiths Medical MD, Inc. (1). The reports were submitted by 16 hospitals between July 2007 and July 2009.

The most frequently reported device problems were:
• Screen displayed dosage did not match dose administered to patient (4)
• Controller malfunction (2)
• Human factors (2)

No reports involved a patient death. Ten of the 17 reports were associated with over-infusion of the prescribed drug and 7 of the 17 reports were associated with under-infusion of the prescribed drug. The patient injuries listed below were reported in 8 of these 17 reports.
• Inadequate pain relief (5)
• Shallow respiration (1)
• Lethargic (1)
• Unresponsive, needed to be revived (1)

Of the reports that listed patient age, 3 had a patient age listed as less than 21 years and 9 had a patient age listed as greater than 21 years. Of the reports that listed patient gender, a total of 8 reports involved female patients and a total of 3 reports involved male patients.

The following table lists the MedSun reports that are described in the device problem summary above.

Adverse Events

Manufacturer	Brand	Model#/Catalog#/Lot#	Event Description
ALARIS Medical Systems, Inc.	Alaris	None/None/None	While instructing the patient on PCA use, I jiggled the patient controller, and heard a beep from the module. I had not touched the button, but the PCA administered a dose anyway.
Hospira Global Medical Affairs	Hospira	None/None/None	Nurse was changing the syringe on the PCA pump. Initially, the syringe would not fit into the cartridge. As she attempted to get the syringe in, each time she made an attempt, the plunger would push medication through the tubing into the patient. What she discovered was that the cartridge had to

			be lifted back into position after removing the previous syringe to get this to fit into the pump. When she finally had gotten the syringe properly in place, the patient was lethargic and nearly unresponsive. She noted that a significant amount of medication had inadvertently been administered. The clamp on the tubing was not closed before adding the new medication. This is a new pump and this is a change in process for the staff. This was not included in the training by the manufacturer.
Hospira Global Medical Affairs	Abott Lab 4100	4100/None/None	Screen displayed usage of 0.8mg. However, upon measurement of syringe, patient possibly used 15-17mg.
Hospira Global Medical Affairs	Abbott Lab 4100	4100/None/None	Per machine, the patient received 0.8mg Dilaudid but, upon RN inspection, it was measured as 12mg. Pt received the wrong dose of the medication.
Curlin Medical Inc.	curlin medical pca pump	203258/None/None	Pt. complaining of pain. It was not well controlled. Pt. controlled bolus was not being delivered. A different pump was tried, but the same issue occurred. Biomed was called and the PCA button and cord were replaced. The patient bolus was then delivered.
Baxter Healthcare Corporation	None	IPUMP/None/None	An Epidural Pump was placed on the patient after surgery. The unit was started in the evening with a rate of 10 ml of continuous flow with no bolus given. The unit

			appears to be delivering the medication, but the patient reported that the pain would not subside. Alternative pain medication was given since the patient was in obvious pain. The anesthesiologist checked the unit the next morning (~11 hrs later) and noted that no medication had been given. However, the unit indicated that 229 ml has been delivered. The epidural pump was pulled from service and another unit was used with the same tubing. The unit was tested by Biomedical Services on the same settings and tested fine. The pump will be sent to the manufacturer for further evaluation.
Cardinal Health	Alaris	8015/None/None	55 ml Fentanyl syringe delivering 4 ml/hr (200mcg/hr) syringe was started and approximately 2.5 hours later, the syringe was found to be almost empty. Patient stable post event. Biomedical Assessment: Problem: Reported problem says: 60ml Fentanyl syringe set to deliver at 4ml/hr started and approximately 2.5 hours later the syringe was empty. The drug infused too quickly. It should have taken 15 hrs to deliver 60ml's. Corrective Actions/Recommendation: The event log from the PCA module shows that it was set to deliver 20 ml/hr instead of the 4 ml/hr as indicated by the nurse. There were no errors in the error logs for

			either the PCU or the PCA module. The pump functioned properly, but was set at the wrong rate.
B Braun Medical Inc.	Patient Controlled Analgesia Pump	None/None/None	Pt.complained of not getting relief from PCA medication. RN realized that most of the medication was still in the bag. Further assessment revealed that the PCA button was not working(i.e. when pushed pt did not receive bolus). Biomedical engineering tested the pump and identified a broken cable as the source of the problem. This has been a frequent problem with these pumps. Biomed believes the cable should be designed to be more flexible. We are also reminding our staff not to tightly wrap the cords for storage.
Baxter Healthcare Corporation	Baxter PCA Pump	None/None/None	Syringe check indicated substantial amount of medication left in syringe. PCA machine evaluated. Although PCA machine indicated it was running and giving appropriate amounts of attempted injections, found PCA machine was not injecting.
IRadimed Corporation	IRADIMED	None/None/None	IRADIMED pump noted to be delivering prescribed bolus infusion over 3 minutes instead of 10 minutes as programmed.
ALARIS Medical Systems, Inc.	Medley	8120/None/None	A pediatric patient was being infused with 0.2mg/ 1 mL concentrated Dilaudid from an Alaris Patient Controlled Analgesic (PCA) pump. At approximately 2200 it was

			noted that the patients respiration rate was shallow (less than 5 breaths/min) with periods of apnea. The oxygen saturation (SpO2) was 77%. The patient was arousable, but having difficulty staying awake. The patient was placed on 2 lpm oxygen and the PCA was withheld. The resident physician was notified. The PCA was changed to an 8 minute lockout cycle (was previously programmed at a 6 minute lockout). The patient continued to have a shallow respiration rate. The resident was updated and assessed the patient. The PCA was discontinued and Narcan was administered. The patient respiration rate increased to around 18 breaths/min, and the SpO2 increased to 98.1%. Lortab was administered at this time. Biomedical Engineering was notified, and the infusion pump PCU and PCA module were tagged and removed from the unit for inspection, and an alternative pump was obtained for the patient. After the incident took place, another RN on the unit instructed the RN that observed the incident to verify the PCA was programmed correctly. Two RNs went to verify the programming of the PCA and noted that it had not been programmed correctly. The PCA was programmed using the 0.1mg/ 1mL

			concentration of Dilaudid rather than the actual 0.2mg/ 1mL concentration stated on the syringe label. The delivery rate was programmed at 0.1 mL for every PCA dose with a 6 minute lockout cycle, so the patient was actually receiving 0.02 mg of Dilaudid with each PCA dose, when only 0.01 mg was ordered. The PCA programming was corrected at this time and the patient improved with no permanent harm noted. Biomedical and Clinical Engineering reviewed the PCA and infusion pump event logs, and verified that on the day of the event (midnight), the PCA was programmed for 0.1mg/ 1mL concentrated Dilaudid. The syringe was labeled as 0.2mg/ 1mL concentration. The concentration was not changed again until approximately 0100 the following day. Therefore, the patient was receiving twice the ordered dose of Dilaudid for an approximate 24-hour period of time. This incident is determined to be a use-error. The patient was given twice the ordered dose of Dilaudid due to an error in programming of the drug concentration on the PCA pump. The patient was stabilized and no further injury occurred. The Alaris PCA and infusion pump were thoroughly examined by Biomedical Engineering after

			the incident and no damage or malfunction was found.
Baxter Healthcare Corporation	AP2	2L3105R/None/None	A Baxter AP2 PCA pump was removed from a "do not touch" box in the Materials Department, and used on patient who was on a ventilator and sedated for medication administration. The hospital does not use this pump anymore. The pump was reading low volume, so the ICU nurse went to change the bag and noticed that the bag was almost full. It was programmed for an 8 cc/hr dosage, but and only 35 cc infused in 23 hour period.
Hospira Global Medical Affairs	LifeCare	None/None/None	The patient became unresponsive with hemodynamic instability. Initially, there was 22 ml in the syringe. An hour and 15 minutes later, there was only 7 ml in the syringe. The patient was unresponsive and was revived with Norepinepherine, Narcan and Lasix. The patient was successfully revived and is currently fine.
Hospira Global Medical Affairs	Lifecare	None/None/None	The patient's medication was ordered, which was Fentanyl PCA 1500 mcg/30ml: 25 mcg per request q5 minutes, 600 mcg/4 hour lockout. The incorrect concentration was programmed into the pump. The syringe was filled with Fentanyl at a concentration of 50 mcg/ml, however the pump was programmed for a concentration of 25 mcg/ml. The patient received twice as much drug as prescribed. He

			had excellent pain control and was feeling fine (he is opiate-tolerant). In review of the pump history, it was noted that the pump settings were checked and verified at the incorrect (25 mcg/ml) concentration five different times in the previous 24 hours. This is a high alert medication, and the two nurse safety check on the programming was not performed. This syringe comes in an empty vial, which requires nursing to program the pump with the dose concentration. The pharmacy does not have the technology in place to print barcodes for empty vials that are filled. Additionally, this product is not available commercially in pre-coded vial that will fit in the Hospira pump.
Hospira Global Medical Affairs	Lifecare	39385/None/None	PCA pump did not alarm occlusion and was clamped for an extended amount of time resulting in the patient not recieving proper/ordered medication for pain management.
Smiths Medical MD, Inc.	CADD Prizm PCS II	CADD Prizm PCS II/None/None	Pt with PCA for abdominal pain. Pump settings in AM were: Hydromorphone 0.2 mg/ml. 50 doses in the container to start with no basal dose, and demand dose of 0.2 mg. Lockout time 10 minutes, with 41.7 mg in the container. Later that evening, it was determined there was a discrepancy with the remaining amount in

			container vs. what pump indicated had been infused. Pump stated reservoir had 24.4 mg remaining after 0.4 mg given. Previously, in the AM, there was 41.7 mg in the reservoir. So, there is a discrepancy of approximately 16 mg. Patient had made 10 attempts. Pump settings were verified. Pt had complained that she had not received adequate pain relief.
Baxter Healthcare Corportation	I Pump	None/None/None	The nurse reported that the Narcotic I pump was not keeping the programmed amount and kept shifting back to previously set settings. In addition, the pump was not maintaining an appropriate history of the amount infused, and then kept alarming "malfunction". It was also noticed the pump kept increasing the amounts for medication to maintain sedation. This unit is not owned by our hospital, it is leased equipment through a separate company. The pump was sent out to the rental company for repairs.

Additional Information:

[1]. Cleveland Clinic. (2009). Patient-Controlled Analgesia (PCA) Pump. Retrieved July 28, 2009, from Cleveland Clinic Foundation Website: http://my.clevelandclinic.org/services/pain_management/hic_pain_control_after_surgery.aspx[26]